CARELLA BYRNE CECCHI
OLSTEIN BRODY & AGNELLO, PC
James E. Cecchi
Donald A. Ecklund
5 Becker Farm Road
Roseland, NJ 07068-1739
Telephone: (973) 994-1700

Liaison Counsel for the Putative Class

KESSLER TOPAZ
MELTZER & CHECK, LLP
Sharan Nirmul
David A. Bocian
Joshua E. D'Ancona
Vanessa M. Milan (admitted *Pro Hac Vice*)
280 King of Prussia Road
Radnor, PA 19087
Telephone: (610) 667-7706

Counsel for Lead Plaintiff Industriens Pensionsforsikring A/S and Lead Counsel for the Putative Class

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

INDUSTRIENS PENSIONSFORSIKRING A/S, Individually and On Behalf of All Others Similarly Situated,

Plaintiff,

v.

BECTON, DICKINSON AND COMPANY, VINCENT A. FORLENZA, THOMAS E. POLEN, and CHRISTOPHER R. REIDY,

Defendants.

Case No. 2:20-cv-02155-SRC-CLW

Hon. Stanley R. Chesler
District Judge

Hon. Cathy L. Waldor
Magistrate Judge

THIRD AMENDED CLASS ACTION COMPLAINT

JURY TRIAL DEMANDED

TABLE OF CONTENTS

Lead Plaintiff Industriens Pensionsforsikring A/S ("Industriens" or "Plaintiff"), by and through its undersigned counsel, brings this action individually and on behalf of all others similarly situated who purchased or otherwise acquired the common stock of Becton, Dickinson and Company ("BD" or the "Company") between November 5, 2019, and February 5, 2020, both dates inclusive (the "Class Period"), and were injured thereby (the "Class"). This action is brought against defendants BD and its current and former executive officers, Vincent A. Forlenza, Thomas E. Polen, and Christopher R. Reidy ("Forlenza," "Polen," and "Reidy," collectively, the "Individual Defendants," and with BD, "Defendants").

Plaintiff alleges the following upon personal knowledge as to itself and its own acts, and upon information and belief as to all other matters. Plaintiff's information and belief is based upon, among other things, the ongoing investigation that Court-appointed Lead Counsel is conducting under Plaintiff's supervision. This investigation includes, but is not limited to, reviewing and analyzing: (i) documents that BD filed with the U.S. Securities and Exchange Commission (the "SEC"); (ii) securities analyst reports about BD; (iii) transcripts of BD investor conference calls and conference appearances; (iv) BD press releases and publicly available slide presentations; (v) press and media reports, including online news sources; (vi) public material obtained in connection with Plaintiff's continuing investigation; (vii) interviews of former BD employees or consultants ("Former Employees" or "FEs"); and (viii) materials obtained through Freedom of Information Act requests.[1] Plaintiff believes that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

[1] For ease of readability while preserving their anonymity, the Complaint uses the terms "he" and "his" in connection with all of the Former Employees.

I. INTRODUCTION

1. In 2019, the Alaris infusion pump system ("Alaris") was a critical product for BD, and had been for years. Alaris was a leading revenue-generator for BD's largest segment, BD Medical, and BD as a whole. It held a dominant position in the infusion pump market, commanding roughly a 70% share, and its market share was growing. Quarter after quarter, BD derived substantial revenues from Alaris itself, and also from a suite of "interoperable" products that BD marketed alongside Alaris that interfaced with the pump system. In BD's financial disclosures and public statements on investor calls and conferences, it called out Alaris as delivering outsized revenues and Company growth, touted the product's increasing market share, and claimed that these sustained trends would continue. Investment analysts who covered BD highlighted Alaris as a core driver and cornerstone of BD's earnings and growth across recent periods and into the future.

2. Then, in the late summer and early fall of 2019—unknown to investors—Alaris's growth, momentum and sales were all but derailed. In meetings with BD in August-October 2019 (the "Pre-Class Period FDA Meetings"), the U.S. Food and Drug Administration ("FDA"), BD's chief domestic regulator, learned the full extent of an array of significant Alaris defects that threatened patient safety. In response, the FDA dealt BD a double blow. It told BD that Alaris should not be shipped to consumers given these major issues, and it said that Alaris would need to obtain a new premarket clearance, or "510(k)," from the FDA for changes needed to fix the device. BD halted Alaris shipments and sales immediately, and future sales were imperiled until the necessary clearance was obtained. In sum, acute device and regulatory issues had caused Alaris sales to freeze, with no clear end in sight.

3. Rather than inform investors of these material developments that were presently impacting Alaris sales and threatened BD's revenues and growth prospects for the foreseeable

future, Defendants did the opposite: they lied to investors. On November 5, 2019, BD held its FY19 earnings call (BD's 2019 fiscal year ("FY19") ended on September 30, 2019, and its first quarter ("Q1") of fiscal year 2020 ("FY20") started on October 1, 2019). On this call, Defendants Forlenza and Reidy disclosed BD's FY20 guidance (the "FY20 Guidance"), in which they asserted that BD's overall revenue growth for FY20 would be 5%-5.5% (or an increase of roughly $900 million over FY19), weighted toward the last three quarters of FY20. The reason for this lopsided revenue curve, according to Defendants, was a temporary hold on shipments of BD's Alaris systems that was in place in the current, Q1 of FY20. They asserted that a significant revenue pickup would occur once Alaris sales and shipments resumed in the second quarter of FY20.

4. Defendants Reidy and Polen offered additional details on this Alaris "ship hold" in their scripted remarks. They also responded to investment analysts who, given the importance of Alaris to BD's overall growth, peppered them with questions trying to grasp the nature of the Alaris issues and the potential impact to FY20 earnings. For example:

a. Reidy said Alaris shipments would be paused during Q1 of FY20 as BD completed certain software "improvements" and "upgrades."

b. The "upgrades," Polen assured investors, were simply part of BD's "process and . . . strategy in the business to continually iterate and make enhancements to the platform."

c. Polen also emphasized the consistent "momentum" in Alaris demand that BD was seeing in FY20.

d. Reidy noted that BD was in discussions with the FDA about the "timing of implementation" of the upgrades and possibly bundling them with other new

software, and then he reiterated that the revenue effect of the ship hold would be merely "to move the timing of some sales from Q1 to the balance of the fiscal year."

e. After an analyst asked for more detail, Reidy explained that, absent Alaris sales and shipments, BD's Q1 revenues would grow just 1%-2%, but in the final three quarters, resumed Alaris shipments and sales would power revenues and allow BD to meet its FY20 Guidance.

5. These statements were materially false and misleading, and intentionally so. As was known to Defendants, the true reason for the ship hold was ***the FDA explicitly informing BD that Alaris should not be shipped*** due to major product safety issues, and that Alaris would need to obtain new pre-market clearance from the FDA (i.e., a 510(k)) for the fixes required to address identified Alaris issues. As one Former Employee who personally represented BD in the Pre-Class Period FDA Meetings where these exchanges occurred put it simply, the FDA "was the impetus for the ship hold."

6. In addition to the FDA's role in driving the ship hold, the need for 510(k) clearance was critical information for investors because the delay inherent in the process of seeking and obtaining such clearance presented a severe risk that BD would be unable to sell Alaris in FY20. (Indeed, according to a Former Employee, BD regulatory executives responsible for Alaris considered 510(k) submissions a "death sentence.")

7. The FDA's position on the need for a 510(k) was not a surprise to BD. In fact, in 2018, BD had twice acknowledged to the FDA in non-public regulatory submissions that the remediation for certain of the Alaris issues that BD and the FDA specifically addressed in the

Pre-Class Period FDA Meetings, including a longstanding "Low Battery Alarm" ("LBA") issue, would need a new 510(k).

8. However, in the fall of 2019, BD was not nearly ready to adequately complete the necessary, voluminous 510(k) submission for the Alaris changes in question. Instead, it had attempted "work-arounds" for device issues—including, with respect to the LBA safety defect, telling consumers to throw out and replace Alaris batteries after two years. But in the Pre-Class Period FDA Meetings, the FDA had put its foot down. And, as reported by the same Former Employee who participated in the meetings, BD was effectively "damned if you do, damned if you don't": the FDA had expressly stated that Alaris should not be shipped with the identified issues, and that fixing at least some of them would require a new 510(k)—but this required a massive submission BD was not yet prepared to make, and which, once submitted, could take months or even years for approval. In fact, BD had represented to the FDA that developing the needed Alaris fixes would take approximately nine months. Preparing, submitting and clearing a 510(k) application would take months beyond that. Thus, the regulatory and product issues underpinning the ship hold were substantial, with no ready solution. This bind was ***already*** impacting BD's revenues from Alaris in Q1 of FY20, and the FDA's position foreclosed any reasonable possibility that Alaris would return to market and contribute revenues within FY20.

9. These facts, known internally at BD, contradicted Defendants' public statements to investors. While Defendants disclosed the ship hold, they withheld the most important facts relating to the reasons for it. They did not disclose that it was the FDA that had driven BD to impose the ship hold. They failed to disclose that the FDA had called for a new 510(k) to clear needed Alaris fixes. They misleadingly glossed over the known impediments to satisfying the FDA (including the need for a 510(k) for required Alaris fixes, which would take significant

time) and resuming Alaris shipments and sales. These obfuscated or omitted facts were necessary to fill out the misleadingly incomplete picture Defendants presented to investors of: (i) the reason for the ship hold; (ii) BD's discussions with the FDA; (iii) when Alaris would resume contributing to Company revenues; and (iv) BD's FY20 Guidance. By concealing these highly material facts from investors, Defendants prevented the market from fairly evaluating the device and regulatory issues that were already choking off Alaris sales, and the true risk that Alaris would continue not to ship for similar reasons, depriving BD of one of its main revenue-generators, during much more of FY20.

10. Throughout the Class Period, Defendants continued to misrepresent the true scope of the product and regulatory issues confronting Alaris and threatening BD revenues. They reaffirmed the FY20 Guidance, which was reliant on robust Alaris sales after shipping resumed; they offered boilerplate warnings of potential risks of regulator actions that could impact product sales, even after the FDA had already caused BD to halt Alaris shipments and defer sales; and they continued to mischaracterize the true nature of the ship hold, and the true outlook for Alaris's return to market. For example, at the Evercore HealthCONx Conference on December 4, 2019, over two months into BD's FY20, Reidy boasted that BD had gained infusion pump market share, "and ***we see that continuing***."[2] When a participant asked about "revenue deferral" for BD's infusion pumps, Reidy asserted that the Alaris situation was a "timing issue" limited to the front end of FY20. Defendants then reaffirmed BD's FY20 Guidance.

11. Investment analysts, focused on BD's mainstay Alaris product, accepted Defendants' misrepresentations about the ship hold and FY20 Guidance, and repeated them in their reports to investors. For example, on November 14, 2019, J.P.Morgan relayed that the

[2] Throughout this document, all emphasis is added unless otherwise noted.

"delayed shipments" of Alaris "that were pushed out to F2Q from F1Q" were "a timing issue rather than a read-through to underlying demand," and described BD as "well positioned to post another year of share gains" in FY20. Wells Fargo similarly reported to investors that the "timing of Alaris pump software upgrade[] in the US will push sales into FQ2-FQ4."

12. In January 2020, Defendants doubled down on their misrepresentations regarding the Alaris issues, ship hold and revenues. On January 14, 2020, an analyst at the JPMorgan Healthcare Conference asked for comment on Alaris "pump shipments" and "guidance from the FDA" relating to the device. Polen responded Alaris had "[f]ully resumed shipping in the first quarter" and added that the situation had played out "***[e]xactly as expected***." Again, Defendants reaffirmed the FY20 Guidance. Then, on January 28, 2020, at BD's Annual Shareholders Meeting, Defendant Forlenza once more reaffirmed the FY20 Guidance and assured shareholders: "[W]e are on track for the full year."

13. Analysts covering BD reflected Defendants' January 2020 representations about Alaris in their reports to investors. For example, on February 3, 2020, Cowen remarked in a research report that BD management had "publicly revealed that discussions with the FDA were completed and [that] Alaris U.S. shipments [had] returned in full during F1Q." Cowen concluded that these factors "bode[] well for the set up relative to expectations and the guidance range."

14. Unbeknownst to investors, Defendants' January 2020 statements were false for the additional reason that BD's resumption of Alaris shipments in the first quarter of FY20 was unapproved and unacceptable to the FDA (consistent with the agency's stated position in the fall of 2019).

15. Specifically, according to Former Employees with direct knowledge, including one who participated in the meeting, in December 2019 the FDA met with BD and asked it to

confirm that Alaris was not shipping. BD did so, as the ship hold was in place at the time. However, in the following days, BD implemented fixes for some of the more minor software anomalies the FDA had learned of—but ***none*** of the many significant issues, including the LBA defect, that BD and the FDA had said would require a new 510(k). Then, shortly before Christmas 2019, BD lifted the ship hold. Defendants resumed shipping Alaris without so much as informing the FDA. This strategy—unilaterally resuming shipments after implementing an incomplete fix of Alaris issues but leaving aside the most serious defects, and failing to seek the 510(k) clearance the FDA said would be necessary, or even consulting with the FDA—was reckless in the extreme.

16. It failed disastrously. Within approximately three weeks, the FDA met again with BD, at which time BD informed the FDA that it had resumed shipping Alaris. According to several Former Employees, including one in attendance at that meeting, the FDA expressed its dismay and disagreement with BD's action. It heard BD's rationale for restarting shipments, and rejected it—and reaffirmed its position stated in fall 2019 that a new 510(k) was required for needed Alaris fixes before it could be shipped. BD reinstated the ship hold.

17. Thus, unknown to investors, BD did not resolve the relevant Alaris issues "[e]xactly as expected" in promptly-concluded discussions with the FDA during Q1 FY20. Rather, BD knew it still needed a major Alaris remediation. As FEs report, the FDA had made it clear that Alaris should not be shipping until the issues were remediated, and would need new 510(k) clearance for the required fixes. Moreover, the FDA had not approved BD's resumption of Alaris sales in first quarter FY20; to the contrary, the agency had not known of BD's action and did not accept it once it learned of what the Company had done, causing BD to quickly re-impose the ship hold.

18. Finally, on February 4, 2020, Defendants once more materially misrepresented the true extent to which Alaris issues were already impacting, and would continue to impact, BD's FY20 revenues. Specifically, BD issued statements regarding certain software problems that could interfere with patient care, which, the Company claimed, would be remediated through a "voluntary recall" consisting of education, training, and a future software upgrade. Critically, the statements did not even suggest that Alaris devices would not be sold or shipped during the action. But, as confirmed by Defendants' subsequent admissions, Defendants already knew that the Alaris ship hold would be reinstated, and sales all but eliminated, for an indefinite period of time. Investors, on the other hand, understood BD's February 4, 2020 statements exactly how Defendants intended—the software issues would not impact Alaris sales or BD earnings—and shrugged. BD's stock price remained artificially inflated.

19. While Defendants were repeating their misleading representations about Alaris and BD's FY20 revenues, Forlenza and Polen were lining their pockets through illegal insider stock sales. Indeed, Forlenza had entered into a stock trading plan in mid-December 2019, and was motivated to keep BD's stock price inflated while he liquidated tens of millions of dollars of his BD holdings in the span of just two months, ahead of his planned retirement at the end of January 2020. By doing so here, Forlenza avoided millions of dollars of losses on those sales.

20. All in, these Defendants reaped a combined ***$58,417,985.36*** in proceeds in less than three months of Class Period sales. Polen took home more than ***$3.749*** million in proceeds, while Forlenza pocketed in excess of ***$54.6 million*** in proceeds. Nearly all of Forlenza's sales came under a stock trading plan he entered into after he and the other Individual Defendants knew or had access to material non-public information about the real reasons and regulatory

issues that had stopped Alaris sales in the first quarter of FY20, and that imperiled the remainder of FY20 Alaris revenues, as well.

21. Defendants' deception came to an end before the market's open on February 6, 2020. On an earnings call, Defendants admitted for the first time that, due to an Alaris remediation plan that BD was "continuing" to work on with the FDA, BD: (i) would resume the ship hold, effectively halting Alaris sales, and earn no revenues from Alaris in FY20; and (ii) was required to submit a comprehensive 510(k) application for multiple Alaris software changes to the FDA.

22. Specifically, providing further detail, Polen revealed to stunned investment analysts that: (i) the FDA was requiring BD to seek 510(k) clearances related to numerous software changes before resuming Alaris sales; (ii) Alaris would be pulled from the market due to the underlying device software and compliance problems; and (iii) the negative revenue impact to BD in FY20 from the lost Alaris sales would be $400 million. Defendants slashed BD's FY20 Guidance as a direct result, stating they were "revising our revenue growth guidance to 2.5% to 3.5%, ***specifically due to the Alaris situation***." Defendants' disclosure thus related directly to facts they had concealed since the start of the Class Period, including the FDA's position that Alaris should not be shipped given its substantial safety and device defects, and that needed Alaris fixes would require 510(k) clearance.

23. Upon Defendants' disclosure on February 6, 2020, BD's stock price dropped $33.74 (nearly 12%) on unusually heavy trading volume, to close at $252.25 that day. Analysts immediately linked the drop to the "unexpected announcement that BDX is working with the FDA on a software remediation plan for the Alaris pump system." Roughly ten billion dollars of shareholder wealth was destroyed in one day.

24. Events after February 6, 2020 indicate the depths of the Alaris issues that Defendants concealed. BD did not file its 510(k) submission for Alaris with the FDA until April 26, ***2021***. As of October 28, 2021, over six months later, the FDA had not granted that 510(k) nor cleared the device for market. In a related disclosure, BD told the market that its planned remediation for the Alaris LBA issue had not yet been approved by the FDA as of July 29, 2021. Additionally, the loss of Alaris sales powerfully impacted BD's earnings in 2020 (and beyond). BD admitted in its Form 10-K for FY20, dated November 25, 2020, that the hold on Alaris shipments had an unfavorable impact on the revenues, operating income and gross profit margins of the Medication Management Solutions ("MMS") unit, BD Medical and BD overall across FY20 (for example, BD Medical's operating income was approximately $550 million lower in FY20 than in FY19).

25. Moreover, the Company's Alaris-related conduct has drawn the attention of the Enforcement Division of the SEC. On May 6, 2021, BD disclosed in its Form 10-Q for the second quarter of FY21 that:

> In February 2021, the Company received a subpoena from the Enforcement Division of the SEC requesting information from the Company relating to, among other things, Alaris™ infusion pumps. The Company is cooperating with the SEC and responding to these requests. The Company cannot anticipate the timing, scope, outcome or possible impact of the investigation, financial or otherwise.

II. JURISDICTION AND VENUE

26. The claims asserted herein arise under Sections 10(b) and 20(a), and 20A of the Securities Exchange Act of 1934 (the "Exchange Act"), 15 U.S.C. §§ 78j(b) and 78t(a), and 78t-1(a), and the rules and regulations promulgated thereunder, including SEC Rule 10b-5, 17 C.F.R. § 240.10b-5.

27. This Court has jurisdiction over the subject matter of this action pursuant to Section 27 of the Exchange Act, 15 U.S.C. § 78aa, and under 28 U.S.C. § 1331, because this is a civil action arising under the laws of the United States.

28. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b) and Section 27 of the Exchange Act, 15 U.S.C. § 78aa. Many of the acts and transactions alleged herein, including the preparation and dissemination of materially false or misleading information to the investing public occurred in substantial part in this District. Additionally, Defendant BD maintains its headquarters and conducts business in this District.

29. In connection with the acts alleged herein, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the United States mails, interstate telephone communications, and the facilities of a national securities exchange.

III. PARTIES AND RELEVANT NON-PARTIES

A. Lead Plaintiff

30. Plaintiff Industriens Pensionsforsikring A/S is one of Denmark's largest pension funds, with at least 400,000 pensioners. As set forth in the certification attached hereto as Exhibit A, Industriens purchased or otherwise acquired BD common stock at artificially inflated prices during the Class Period and was damaged as a result of the conduct alleged herein.

B. Defendants

1. Corporate Defendant BD

31. Defendant BD is a New Jersey corporation headquartered in Franklin Lakes, New Jersey. BD is a medical technology company engaged primarily in manufacturing and selling medical devices, instrument systems, and reagents. The Company's common stock trades on the New York Stock Exchange ("NYSE") under the ticker symbol "BDX."

32. BD's fiscal year begins on October 1 and ends September 30 of the following calendar year, and is comprised of first fiscal quarter (October 1 - December 31), second fiscal quarter (January 1 - March 31), third fiscal quarter (April 1 - June 30), and fourth fiscal quarter (July 1 - September 30).

33. During the Class Period and for some years before, BD's operations consisted of three business segments: BD Medical, BD Life Sciences, and BD Interventional.

34. BD Medical was BD's largest and most important segment in terms of revenue. It reported operating income of $2.824 billion in FY19, $2.624 billion in FY18, and $1.907 billion in FY17 and accounted for more than half of the Company's total revenue in each of the last three fiscal years: $9.064 billion in FY19 (representing approximately 52% of BD's total FY19 revenue), $8.616 billion in FY18 (representing approximately 53% of BD's total FY18 revenue), and $7.419 billion in FY17 (representing approximately 61% of BD's total FY17 revenue).

35. At all relevant times, the MMS unit was one of BD Medical's two largest units. The MMS unit focused on infusion systems (i.e. Alaris) and dispensing technologies. Moreover, during BD's FY19 (which concluded September 30, 2019, shortly before the Alaris ship hold commenced), MMS was by far the fastest growing unit within BD Medical, for example: (i) growing 5.9% in Q2 FY19, while the next fastest growing unit increased 1.1% and all others shrank; and (ii) growing 7.7% in Q3 FY19, while other units grew by 3.1%, 0.8%, and -0.4%. BD highlighted the MMS unit's growth in its financial disclosures in FY19, for example, stating that BD Medical's sales numbers reflected sales growth "attributable to" the MMS unit's growth.

a. Organizational Structure of BD's Regulatory, Quality and R&D Functions That Oversaw Alaris Matters

36. As noted above, BD Medical was BD's largest operating segment, accounting for over half of BD's revenues in FY 2017, 2018 and 2019. The MMS unit was one of four

operating units within BD Medical, one of the two largest, and, in 2019, the unit with the largest revenue growth.

37. As discussed in further detail below, BD and its medical technology products and operations were subject to regulation by the FDA and other agencies, and BD was required to maintain a "quality system" for Alaris product design, manufacturing and distribution processes in order to comply with all applicable FDA regulations and quality system requirements.

38. Within BD, MMS was the unit that had primary and direct responsibility for matters of Quality, Regulatory Affairs, Research & Development ("R&D"), Business (i.e., sales and marketing), and other functions with respect to the products designed, manufactured, and distributed by MMS, including Alaris.

39. Each function within the unit had a head executive who oversaw the entirety of the function within MMS. The relevant key functions, and their executive leadership, were as follows:

a. Quality: At all relevant times, the Quality function at MMS was led by Keith Mclain, Global Head of Quality for MMS. That position reported to the Senior Vice President ("SVP") of Quality for BD Medical, who reported in turn to the Chief Quality Officer for BD. Mclain was the executive with primary day-to-day authority and responsibility for Quality and compliance matters related to Alaris at BD.

b. Regulatory Affairs: Until November 1, 2019, the Regulatory Affairs function at MMS was led by Jessica Smith, the Global Head of Quality for MMS. Between November 2019 and February 2020, that position was not yet filled and its responsibilities were handled by Mark O'Donnell, SVP of Regulatory

Affairs for BD Medical. In February 2020, Neelu Gibson filled the role. Although there was some turnover in the roles in the 2019-2020 timeframe, the Global Head of Regulatory Affairs for MMS reported to the SVP of Regulatory Affairs for BD Medical, who, in turn, reported to the Executive Vice President ("EVP") of Regulatory Affairs for BD. The Global Head of Regulatory Affairs for MMS was the executive with primary day-to-day responsibility for Regulatory Affairs matters related to Alaris at BD.

c. R&D: At all relevant times, the R&D function at MMS was led by Steven Smith, Global Head of R&D for MMS.

d. Business: At all relevant times, the Business function at MMS was led by Ranjeet Banerjee, Global Head of MMS Business. That position reported to Alberto Mas, head of the BD Medical Business, who, in turn, reported to BD's President and Chief Operating Officer ("COO") (and later, Chief Executive Officer ("CEO")), Defendant Polen.

40. FE-6 (as defined below (paragraph 53), an executive in the Quality function in the MMS unit with responsibilities for Alaris before and during the Class Period) reports that all of the MMS functional heads served on the MMS Leadership Team, which met at least monthly. This was reflective of the extensive overlap between the functional areas and the regular need for coordination between the MMS functions on product matters.

41. According to FE-6, in 2018-2020, the MMS functional groups "by necessity worked together" to address Alaris product and regulatory issues that arose.

42. In meetings with the FDA concerning Alaris issues, BD was regularly represented by relevant executives from MMS. In a series of pre-Class Period meetings between the FDA

and BD regarding Alaris issues in the late summer and early fall of 2019, BD was primarily represented by Keith Mclain, Global Head of Quality for MMS, and Jessica Smith, Global Head of Regulatory Affairs for MMS, along with certain of their direct reports.

2. Individual Defendants

43. Defendant Forlenza served as BD's CEO from October 2011 until January 2020, when he retired. Forlenza was appointed Chairman of the Board in July 2012, and currently serves as the Executive Chairman of the Board. As BD's CEO, Forlenza was responsible for the Company's day-to-day management and control. Throughout the Class Period, Forlenza approved and signed BD's periodic filings with the SEC and regularly spoke to investors and securities analysts about BD's operations and financial performance in press releases, conference calls and at meetings and conferences, after personally participating in the preparation and finalization of his public statements on behalf of BD. Forlenza sold 198,137 shares of BD common stock between December 12, 2019 and January 28, 2020, while in possession of material, non-public information, for proceeds of over $54 million.

44. Defendant Polen rejoined BD in 2009 and currently serves as the Company's President, CEO and Chairman of the Board. Polen became CEO in January 2020, replacing Forlenza. Polen became BD's President in 2017. Prior to January 2020 and during the Class Period, Polen also served as BD's COO. In each of these roles, Polen was responsible for the Company's day-to-day management and control. Throughout the Class Period, Polen regularly spoke to investors and securities analysts about BD's operations and financial performance—including specifically about the Alaris ship hold and the Company's related interactions with the FDA. Polen personally participated in the preparation and finalization of his public statements on behalf of BD, including his statements about Alaris and related interactions with the FDA. Moreover, from October 2014 to April 2017, Polen was the EVP and President of the BD

Medical segment, during which he led the acquisition of CareFusion Corp. ("CareFusion"). Polen sold 13,907 shares of BD common stock in December 2019, while in possession of material, non-public information, as alleged herein, for proceeds of over $3.7 million.

45. Throughout the Class Period, Defendant Reidy served as BD's EVP, Chief Financial Officer ("CFO"), and Chief Administrative Officer, positions he had held since July 2013. Reidy was replaced as BD's CFO in August 2021. In his role as BD's CFO, Reidy was responsible for the Company's day-to-day management and control. Throughout the Class Period, Reidy approved and signed BD's periodic filings with the SEC and regularly spoke to investors and securities analysts about the Company's operations and financial performance—including specifically about the Alaris ship hold and the Company's related interactions with the FDA. Reidy personally participated in the preparation and finalization of his public statements on behalf of BD, including his statements about Alaris and related interactions with the FDA.

C. Cardinal Health and CareFusion

46. At relevant times, Cardinal Health, Inc. ("Cardinal Health") was a health care services company specializing in the distribution of pharmaceuticals and medical products. It acquired Alaris in May 2004 as part of its acquisition of ALARIS Medical Systems Inc. In 2009, Cardinal Health spun off CareFusion, a San Diego-based medical technology company which was then manufacturing Alaris. CareFusion operated as a publicly traded company until it was acquired by BD in 2015, after which time, BD designed, manufactured and sold Alaris.

D. Former Employees Reporting Relevant Facts

47. Numerous Former Employees, or FEs, report relevant facts, circumstances and events related to Alaris and BD's interactions with the FDA in and around the Class Period. Former BD employees who had responsibilities and roles related to the events and circumstances at issue include the following:

48. FE-1 worked as a senior engineer at BD from 2015 through the summer of 2019. In 2019, he worked in BD Medical's MMS unit, which developed, manufactured and marketed Alaris. As a primary part of his responsibilities in 2019, he worked directly on developing and implementing changes to Alaris software.

49. FE-2 worked as a Manager in the Quality function from 2015 until early 2019 in BD Medical's MMS unit. The MMS unit included different related functions (as discussed in further detail in paragraphs 38-41), including a Quality group that oversaw quality systems and operations quality. FE-2 had responsibilities for managing BD's quality systems in the MMS unit, under Quality group head Keith Mclain.

50. FE-3 worked as an Associate Director in engineering from mid-2016 through late 2019 in BD Medical's MMS unit. FE-3 worked directly on Alaris engineering projects during his tenure.

51. FE-4 worked as a Quality Assurance Manager from mid-to-late 2019 in BD Medical's MMS unit. FE-4 explained he was specifically hired in mid-2019 to help BD prepare for an anticipated FDA inspection and review. His primary responsibility was to conduct reviews of quality systems at Alaris production facilities and produce reports concerning issues he identified in the quality systems related to Alaris.

52. FE-5 worked in numerous roles, including as a Manager, Regulatory Affairs, from at least 2016 through the latter half of 2020, in BD Medical's MMS unit. He worked in the unit's Regulatory function, which was led by Jessica Smith, BD's Global Head of Regulatory Affairs for MMS. FE-5 worked extensively, often full-time, on regulatory issues concerning Alaris. Alaris was the sole or primary product on which FE-5 focused in his work. Among other projects, FE-5 worked on regulatory analyses related to new upgrades to Alaris or potential

device fixes and performed in-depth assessments of whether Alaris changes required 510(k) clearance. FE-5 often regularly presented his conclusions in meetings to BD executives in both San Diego (the site of the MMS unit) and Franklin Lakes, New Jersey (the site of BD corporate headquarters). According to FE-5, regulatory affairs executives responsible for Alaris referred to the FDA's 510(k) clearance process as "a death sentence."

53. FE-6 was a senior executive in the Quality function at BD Medical's MMS unit from 2016 through the spring of 2020. He had overall leadership responsibilities for the Quality function for MMS products, specifically including Alaris. He reported that Alaris occupied roughly 90% of his focus at work, given the extent of the issues with the product, and the high significance of the Alaris platform to BD. In 2019-2020, FE-6 reported to BD Medical's Head of Quality, Boris Shkolnik, and regularly reported as well to BD's overall Head of Quality, Pierre Boisier, both of whom worked at BD's corporate headquarters.

54. FE-7 was a Program Manager, R&D, at BD Medical's MMS unit from at least 2015 through the spring of 2021. He worked within the MMS unit's R&D function group, developing software to address Alaris issues and changes. FE-7 worked "full time on Alaris." Among other responsibilities, he prepared "change orders" that set and governed the scope of software changes made to Alaris, working closely with the MMS Quality, Regulatory and Business function teams to define exactly what the changes should be. FE-7 also was responsible for Alaris labeling changes or potential changes, and for documenting changes made to the device in device files. FE-7 worked on developing potential software fixes for the Alaris LBA issue in 2019.

55. FE-8, an Associate Director, Regulatory Affairs, started working at BD in 2018, and worked at BD Medical's MMS unit from late 2019 through the spring of 2021. FE-8 had

direct responsibilities for: (i) regulatory projects related to a next generation infusion pump; and (ii) preparation of the 510(k) submission for Alaris, which was ongoing in 2019-2020. FE-8 reported to Katie Walton, Senior Director of Regulatory Affairs for the MMS unit. Walton's purview was regulatory matters involving Alaris. Walton reported to Jessica Smith, BD's Global Head of Regulatory Affairs for MMS, and later Neelu Gibson, who replaced Smith in that role in February 2020. Walton and FE-8 also worked directly with Mark O'Donnell, Vice President ("VP") of Regulatory Affairs for BD Medical, on preparations and strategy for the Alaris 510(k) submission.

56. FE-9 was an Associate Director, Quality, at BD Medical's MMS unit from the spring of 2019 through early 2021. FE-9 reported to Bhupesh Mahendru, Senior Director of Quality for MMS. Mahendru reported to BD's Global Head of Quality for MMS, Keith Mclain. FE-9 and his team: (i) worked on Alaris analyses and risk assessments to identify issues in existing and prior product models; and (ii) developed Alaris device interface and software solutions for purposes of developing a next generation infusion pump system. FE-9's team from the Quality function worked closely with individuals from the MMS R&D function on these projects. FE-9's direct supervisor, Mahendru, met periodically with the FDA about Alaris. Mahendru regularly informed FE-9 about what was said in those FDA meetings, in particular in the 2019-2020 timeframe.

57. FE-10 was a Senior Regulatory Compliance Specialist at BD Medical's MMS unit from early 2017 through the summer of 2021. FE-10 worked within the Quality function, and reported to Michelle Badal, VP of Regulatory Compliance, Quality, in the MMS unit. Badal reported to BD's Global Head of Quality for MMS, Keith Mclain. FE-10 worked exclusively on Alaris-related projects from 2017 to 2020. FE-10 reviewed and handled complaints and reports

from the field regarding Alaris. He recorded complaint matters in BD's internal Trackwise system. When he reviewed a complaint and deemed it reportable to the FDA, he would create a Medical Device Report ("MDR") and file an electronic submission ("EMDR") with the FDA. FE-10 also had responsibilities for handling FDA "request letters" seeking information on Alaris matters from BD, and preparing BD's responses to the FDA. FE-10's direct supervisor, Badal, met periodically with the FDA about Alaris. Badal regularly informed FE-10 about what was said in those FDA meetings, in particular in the 2019-2020 timeframe.

58. FE-11 was a Manufacturing Engineer at BD from late 2017 through late 2020. FE-11 worked on engineering projects for the Alaris pump for the entirety of his tenure at BD, at BD Medical's MMS facility in San Diego. FE-11 also worked closely with personnel from related MMS functions, especially the Quality function, in carrying out his work.

59. FE-1, FE-2, FE-3, FE-4, FE-5, FE-6, FE-7, FE-8, FE-9, FE-10 and FE-11 collectively recount facts about the product and regulatory issues confronting BD's mainstay Alaris product, and events and circumstances within the BD business unit responsible for Alaris, MMS, in and around the Class Period, as set forth below in paragraphs 122-192.

IV. FACTUAL ALLEGATIONS OF DEFENDANTS' FRAUD

A. Background on the Use and Regulation of Infusion Pumps

1. Modern Infusion Pumps

60. Infusion pumps are electronic, external medical devices that deliver fluids into a patient's body in a controlled manner. They are commonly used to deliver blood, nutrients, or medications such as insulin, antibiotics, chemotherapy drugs, and pain relievers.

61. To function properly, infusion pumps depend on device hardware—mechanical parts and electrical components—as well as specialized software that governs device operations. Infusion pumps are typically operated by trained healthcare workers using a built-in software

interface. Infusion pump interfaces control and allow for programming of the amount, timing, frequency, limits, and other aspects of fluid delivery. Modern infusion pumps are often paired with related devices and software platforms in comprehensive "medication management" systems.

62. Further, today's smart pumps (including Alaris) rely on a range of software-based safety features, such as electronic alarms that activate when there is a risk of an adverse drug interaction, infusion interruption, or low battery.

63. Because infusion pumps are frequently used to administer critical fluids including high-risk medications, hardware or software failures can have significant implications for patient safety. For instance, if an alarm indicating that an infusion is ending or that power to the device has been lost fails to sound due to a software error, a nurse or clinician may not receive sufficient notification of the event. When this occurs in a high-risk population, or when the pump is providing critical or potentially risky medication, an alarm failure or other software failure could result in serious injury or death.

2. Federal Regulation of Infusion Pump Devices

64. The products, development activities, and manufacturing processes of medical device manufacturers are subject to regulation by the FDA pursuant to the Food, Drug, and Cosmetic Act (the "FD&C Act"), as amended by the Medical Device Amendments of 1976 (the "MDA").

65. The MDA separates regulated medical devices into three different classes based, among other things, on their riskiness to patients' safety. Infusion pumps, including the Alaris line, are "Class II" medical devices. According to the FDA, Class II devices possess a potential for dangerousness and thus "general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness." 21 U.S.C. § 360c(a)(1)(B).

66. The primary mechanism by which the FDA oversees and regulates the design and manufacture of medical devices, including changes to a device's design and software, is the FDA's Quality or Quality System regulations. Medical device manufacturers, including BD, must establish and follow quality systems procedures to ensure that their products consistently meet applicable requirements and specifications known as current good manufacturing practice ("cGMP") standards. Regardless of whether any other specific clearance or approval is required, a manufacturer's processes related to device design and modification must always comply with all relevant Quality System regulations and related guidance.

67. The FDA requires manufacturers to document and keep records related to software or other design changes to Class II medical devices. Specifically, for example, the FDA's Quality System regulations require that a manufacturer maintain a process whereby it documents all analysis, testing, and decisions associated with software changes to its medical devices. *See, e.g.*, 21 C.F.R. § 820.30 (manufacturer must establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met); 21 C.F.R. § 820.70 (manufacturer shall establish and maintain procedures for changes to a specification, method, process, or procedure); 21 C.F.R. § 820.181 (manufacturer must document changes and approvals in the device master record); *see also Deciding When to Submit a 510(k) for a Software Change to an Existing Device*, U.S. Food & Drug Admin., Oct. 25, 2017 ("510(k) Software Guidance").

68. If requested by the FDA, a manufacturer must be able to provide documentation and communicate in a clear and coordinated manner regarding actual, proposed, or potential changes, including software changes, to regulated devices. The manufacturer must also provide sufficient documentation regarding all related and mandatory device testing and analysis.

69. Under applicable Quality System regulations and cGMP standards, medical device manufacturers are also required to establish and maintain procedures for implementing corrective and preventive actions. These procedures must include processes for, among other things: (i) detecting recurring quality problems; (ii) investigating product nonconformities; (iii) identifying actions to correct and prevent recurring nonconformities; (iv) verifying and validating corrective and preventive actions; and (v) appropriately recording all relevant information regarding quality problems and corrective and preventive action.

70. The FDA may conduct inspections at any time to determine compliance with the Quality System regulations and cGMP standards. The failure to comply with regulatory standards may result in, among other things, the issuance of a Form 483—a form used by the FDA to notify manufacturers of significant objectionable conditions discovered during inspections that may constitute violations of the FD&C Act and related regulations—a warning letter, fines, seizure or recall of products, or product bans. The FDA may also seek a court order enjoining individuals and/or corporations from continuing to violate the FD&C Act or even recommend criminal prosecution by the Justice Department.

71. BD was required to comply with the Quality System regulations and cGMP standards with respect to Alaris at all relevant times prior to and during the Class Period.

3. The 510(k) Clearance Requirement

72. As Class II medical devices, infusion pumps including Alaris must be approved for distribution and monitored with respect to device changes through the FDA's Premarket Notification 510(k) program (the "510(k) Program"). Specifically, Section 510(k) of the FD&C Act and its implementing regulations requires a device manufacturer to obtain approval from the FDA for any Class II medical device it wishes to manufacture and market: (i) when introducing a device into commercial distribution for the first time; or (ii) when there is a change or

modification to a cleared device that could significantly affect its safety or effectiveness. This is known as premarket clearance or a "510(k)."

73. To obtain clearance through the 510(k) Program, the manufacturer must demonstrate that its device is at least as safe and effective as, or "substantially equivalent" to, an existing device that has already been approved. When a manufacturer is looking to change a previously approved Class II device, it must obtain a new 510(k) insofar as it makes: (i) "[a] change or modification in the device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design . . . ."; or (ii) "[a] major change or modification in the intended use of the device." 21 C.F.R. § 807.81(a)(3).

74. Therefore, a 510(k) submission package must contain all relevant design documentation, testing data, and other information necessary to allow the FDA to review the manufacturer's claim.

75. A manufacturer seeking 510(k) clearance must submit a 510(k) application to the FDA at least ninety days before it intends to begin marketing the device. 21 C.F.R. § 807.81(a). The FDA's review process normally proceeds in several steps and often takes a significant amount of time to complete.

76. The first step is Acceptance Review, an initial review by the FDA for the facial completeness of the application and supporting package. The FDA aims to provide its Acceptance Review result within fifteen days of submission. The possible results are "Refuse to Accept" (based on inadequate supporting documentation); acceptance (the 510(k) was accepted for Substantive Review); or incomplete acceptance review, and the 510(k) is therefore under Substantive Review. Substantive Review follows for accepted applications. It normally entails an iterative exchange of questions, answers and communications regarding the application

between the FDA and the manufacturer. These substantive interactions should occur within sixty days of the submission. If sufficient information is provided by the applicant in this stage of the review, the FDA aims to complete its review and make a 510(k) determination within ninety days of the application. If instead, as often happens, the FDA makes a request for additional information to support its review of the 510(k) application, the submission is placed on hold, and the applicant has 180 days to provide the information. If the requested information is not completely provided within 180 days, the 510(k) is considered withdrawn. If it is provided, the FDA's Substantive Review process resumes.

77. The FDA's goal is to provide 510(k) decisions within ninety calendar days, *excluding* days the submission was on hold pending information requests by the FDA. As a practical matter, obtaining 510(k) clearance often takes longer than that, once the submission goes in (for example, the Alaris 510(k) application BD ultimately submitted here was filed on April 26, 2021, but as of October 28, 2021, the FDA had not yet issued 510(k) clearance).

78. Before the manufacturer can market the device, it must obtain an order from the FDA that clears it for commercial distribution. If the FDA is unable to determine that a device is sufficiently safe and effective or substantially equivalent to a predicate device based upon the manufacturer's application and supporting documentation, the manufacturer will be required to resubmit its 510(k) application with new data, and the device will be barred from the market until it is cleared. *See generally Premarket Notification 510(k)*, U.S. Food & Drug Admin., https://www.fda.gov/medical-devices/premarket-submissions/premarket-notification-510k.

79. A manufacturer has an ongoing responsibility for monitoring when a 510(k) application must be submitted with respect to a change or modification to a device. To specifically assist both manufacturers and the FDA in determining when a software change to a

Class II device requires submitting a 510(k) application and obtaining FDA clearance, the FDA has issued formal guidance in the 510(k) Software Guidance.

80. The 510(k) Software Guidance provides instruction, including examples regarding the various types of software changes that clearly require new 510(k) clearance. Such changes include where: (i) "the change create[s] or necessitate[s] a new risk control measure or a modification of an existing risk control measure for a hazardous situation that could result in significant harm"; and (ii) "the software change could significantly affect clinical functionality or performance specifications that are directly associated with the intended use of the device."

81. The 510(k) Software Guidance makes clear that even if a given change does not itself require 510(k) clearance, the ***cumulative*** impact of discrete software changes over time can result in the modified device no longer being substantially equivalent to a predicate device. In that circumstance, a new 510(k) clearance is required. In contrast, the 510(k) Software Guidance identifies other, limited software changes as not requiring a new 510(k) submission and clearance, such as "a change made ***solely*** to strengthen cybersecurity" or "a change to the software [that] ***only*** restores the device to the specifications of the most recently cleared device." Even changes falling outside of the 510(k) clearance requirement must continue to comply fully with the FDA's Quality System regulations and cGMP standards.

4. Medical Device Reporting and Product Recalls

82. With respect to marketed devices, the FDA requires medical device manufacturers such as BD to monitor adverse events and product defect reports (which commonly come via customer complaints regarding device issues or failures) and to investigate and redress identified product defects. As FDA guidance for manufacturers explains, the MDR regulation, 21 C.F.R. § 803, requires manufacturers and device user facilities to report certain of these device-related adverse events and product problems to the FDA, including when they

become aware that: (i) any of their devices may have caused or contributed to a death or serious injury; or (ii) their device has malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

83. When a company learns of a defect affecting one of its medical devices, the FDA directs that the company may do one of three things: (i) propose a correction; (ii) remove the product from the stream of commerce; or (iii) voluntarily recall the product.

84. The FDA uses the term "recall" when a manufacturer takes a correction or removal action to address a device issue that causes it to violate FDA requirements. According to the FDA, a recall is appropriate when a medical device is defective and/or could be a risk to health. In some circumstances, corrections related to voluntary recalls may be implemented while the device continues to be marketed and remains in use and available in the field.

85. The FDA classifies device recalls based on the degree of risk associated with the issue. A Class I designation, the most serious, indicates that there is a reasonable chance that a defective product will cause serious health problems or death. A Class II designation indicates that a product may cause a temporary or reversible health problem, or that there is a slight chance that it will cause serious health problems or death. A Class III designation indicates the defective product is not likely to cause any health problem or injury. The FDA monitors device recalls for effectiveness.

B. Alaris at BD

1. Acquisition

86. On October 5, 2014, BD entered into an agreement and plan of merger with CareFusion. The acquisition closed for $12.2 billion on March 17, 2015. CareFusion became a wholly-owned subsidiary of BD. Through the acquisition, BD acquired CareFusion's principal

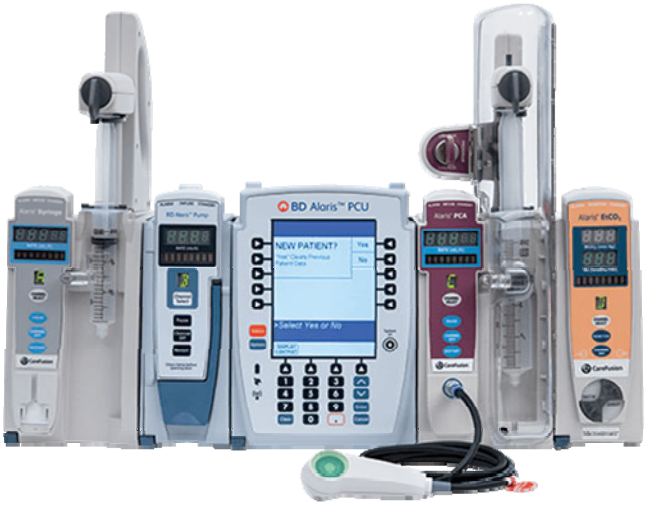
product lines, Alaris and the Pyxis automated dispensing system (Pyxis is an automated movable cabinet that stores prescription medications accessed by healthcare providers).

87. CareFusion was absorbed into the BD Medical segment, doubling its size. Since 2015, BD Medical, through its key MMS unit, has manufactured Alaris, Pyxis, and supporting products that operate in conjunction with Alaris pumps.

88. As explained in more detail below, Alaris is compatible with several other BD Medical products and is the cornerstone of the multi-device MMS product suite whose horizontal integration or "interoperability" (as BD called it) the Company regularly touted to the market.

2. The Alaris Infusion Pump System

89. The Alaris infusion pump and vital signs monitoring system may be built out as depicted here:



90. The center module is the Alaris PC Unit (the "PC Unit"), which provides the main user interface and power supply for the infusion and monitoring modules. Every Alaris infusion system starts with the PC Unit. The PC Unit has wireless data transfer capabilities. Healthcare professionals can build a specialized infusion pump by attaching various infusion modules to the

PC Unit depending on the type of medication and precision required. The screen and keyboard are designed to allow clinicians to gather and respond to intravenous medication data.

91. Clinicians can attach up to four pump modules to a single PC Unit, allowing four different infusions. At relevant times there were three primary infusion modules: (i) the standard pump, Alaris Pump Module, which allows for continuous or intermittent delivery of fluids, medications, blood, and blood products to adult, pediatric, or neonatal patients; (ii) the precision pump, Alaris Syringe Module, which syncs with the PC Unit and combines precision instrumentation to help ensure accurate medication delivery; and (iii) the specialized module for pain medication, Alaris PCA, which has additional safety features, such as respiratory monitoring, and allows patients to press a button to receive additional medication. Each module utilizes software that may periodically require updates.

3. Alaris's Pre-Class Period Regulatory Status and LBA Issue

92. Nine years prior to BD's acquisition of Alaris, on August 15, 2006, Cardinal Health, which then manufactured Alaris, initiated a recall of numerous models due to the potential for over-infusion caused by a software issue. In order to resolve a complaint filed by the U.S Department of Justice which followed, Cardinal Health entered into a consent decree with the FDA on February 7, 2007, which outlined the processes it was to follow to resume manufacturing and selling Alaris pumps. The consent decree was amended in February 2009 to include all Alaris infusion pumps (the "Amended Consent Decree"). After being spun off from Cardinal Health, CareFusion continued to manufacture and market Alaris under the Amended Consent Decree.

93. After acquiring Alaris, BD was subject to the Amended Consent Decree with respect to all Alaris pumps. The Amended Consent Decree remained in effect during the Class Period.

94. In addition, BD's medical devices were subject to the FDA's regulatory oversight and Quality System requirements discussed above. As BD noted in its 2019 Form 10-K:

> BD's medical technology products and operations are subject to regulation by the U.S. Food and Drug Administration ("FDA") and various other federal and state agencies, as well as by foreign governmental agencies. These agencies enforce laws and regulations that govern the development, testing, manufacturing, labeling, advertising, marketing and distribution, and market surveillance of BD's medical products. The scope of the activities of these agencies, particularly in the Europe, Japan, and Asia Pacific regions in which BD operates, has been increasing.
>
> BD actively maintains FDA/ISO Quality Systems that establish standards for its product design, manufacturing, and distribution processes. Prior to marketing or selling most of its products, BD must secure approval from the FDA and counterpart non-U.S. regulatory agencies. Following the introduction of a product, these agencies engage in periodic reviews and inspections of BD's quality systems, as well as product performance and advertising and promotional materials. These regulatory controls, as well as any changes in FDA policies, can affect the time and cost associated with the development, introduction and continued availability of new products. Where possible, BD anticipates these factors in its product development and planning processes. These agencies possess the authority to take various administrative and legal actions against BD, such as product recalls, product seizures and other civil and criminal sanctions. BD also undertakes voluntary compliance actions, such as voluntary recalls.
>
> * * *
>
> Following the introduction of a product, [the FDA] also periodically review[s] our manufacturing processes and product performance. Our failure to comply with the applicable good manufacturing practices, adverse event reporting, and other requirements of these agencies could delay or prevent the production, marketing or sale of our products and result in fines, delays or suspensions of regulatory clearances, warning letters or consent decrees, closure of manufacturing sites, import bans, seizures or recalls of products and damage to our reputation. More stringent oversight by the FDA and other agencies in recent years has resulted in increased enforcement activity, which increases our compliance risk.

As discussed below in paragraphs 319-328, this and similar warnings during the Class Period that FDA requirements "***could*** delay or prevent" the marketing or sale of its products were materially misleading insofar as, *inter alia*, at the time these statements were publicly made,

these risks had already materialized in the FDA expressly calling for the Alaris ship hold and a new 510(k), prior to the Class Period.

95. As a Class II medical device, Alaris was subject to the FDA's 510(k) requirements at all relevant times. It first received 510(k) premarket clearance from the FDA on June 21, 1995. Since 2002, six different 510(k) applications were filed and approved for Alaris changes. BD did not obtain 510(k) approval for changes it made to Alaris between March 2015 and the end of the Class Period.

96. Alaris was periodically the subject of device recalls. One Alaris recall in 2016-2017 concerned a low battery alarm or LBA issue that affected patient safety. Specifically, BD initiated the LBA-related recall in November 2016, which the FDA designated as Class II in March 2017. The recall impacted over half a million Alaris PC Units and was caused by a software error that resulted in the low battery and very low battery alarms failing to trigger. When functioning properly, the low battery alarm would activate when thirty minutes and five minutes of estimated battery runtime remained, and then when the battery was discharged which indicated that the battery was depleted. The error resulted in no alarms sounding prior to the battery discharge alarm. This failure resulted in the device immediately shutting down without prior warning, stopping the infusion. The LBA software error and defect underlying this recall were ***never*** adequately corrected by the end of the Class Period.

97. Furthermore, in September 2018, the FDA issued a non-public regulatory letter on a Form 483 to BD that identified significant objectionable conditions and quality system deficiencies related to Alaris that the FDA found when inspecting BD's San Diego CareFusion facilities, where many Alaris-related operations are centered, between July and September 2018 (the "2018 Form 483"). Among other deficiencies, in the 2018 Form 483 the FDA identified

continuing, significant problems related to the Alaris LBA issue that was the subject of the recall in November 2016-March 2017.

98. Specifically, the FDA found that the supposed fixes BD had implemented for the LBA issue and 2016-2017 recall had not remedied the problem. It noted, for example, recurring complaints from the field and other indicia that BD's LBA remediation had not been effective.

99. BD did not publicly disclose its receipt of the 2018 Form 483, nor the FDA's finding that the LBA issue had not been adequately resolved through the prior recall. Thus, leading into the Class Period, investors were unaware of the escalating regulatory issues confronting Alaris. As noted further below, the FDA and BD specifically further addressed the LBA issue in the Pre-Class Period FDA Meetings in late summer/early fall 2019.

4. Defendants Trumpet Alaris's Contributions to BD's Performance and Growth

100. Since acquiring Alaris, BD regularly touted the product's commercial success, and Alaris's integral role in driving revenue growth for BD Medical (through its MMS unit) and for BD as a whole.

101. After BD acquired Alaris, on March 17, 2015, in an investor presentation entitled "A Leader in Medication Management and Patient Safety," BD hailed Alaris and Pyxis as "Key Brands" that would now make up BD's "Key Platforms" in BD Medical and the MMS unit. Alaris swiftly became the linchpin to BD's growth strategy in BD Medical, now BD's largest segment, and up through FY19, Alaris's share of the infusion pump market grew.

102. Moreover, in addition to selling Alaris itself, BD also regularly promoted Alaris and a related suite of BD products that offered interoperability with Alaris as a key to BD's success in the medication management space.

103. For example, in 2015, BD told investors it would leverage its Alaris and Pyxis platforms together by connecting them though BD's HealthSight Viewer, a web-based pharmacy operations database that can combine data from the Pyxis and Alaris systems into a single view. BD said this interoperability enabled it to provide "end-to-end solutions" for pharmacy to patient tracking, which could aid hospitals to identify bottlenecks in pharmacy fulfillment, optimize medication availability, and provide visibility into errors and medication theft. According to BD, when a consumer bought one of the devices in the suite, the interoperability feature would make it more likely that they would buy the others as well. Thus Alaris (and Pyxis) would drive growth in MMS and BD Medical. Between 2015 and 2019, they did.

104. In a steady drumbeat of public statements to investors, BD routinely touted the fact that BD Medical's growth was attributable to strong growth in sales of the MMS unit's infusion and dispensing products, and specifically Alaris.

105. For example, in its Form 10-K for FY18, dated November 21, 2018, BD asserted that the "Medical segment's underlying revenue growth was largely driven by sales of" two product groups, one of which was "dispensing and infusion systems," i.e., Alaris.

106. Similarly, in BD's Form 10-Q for the second quarter of FY19, dated May 9, 2019, BD reported that BD Medical's revenues "reflected sales growth attributable to the Medication Management Solutions unit's installations of infusion systems." BD repeated the assertion about Alaris sales driving BD Medical growth in its Form 10-Q for the third quarter of FY19, released August 6, 2019, three months before the imposition of the Alaris ship hold.

107. Likewise, at investor conferences and on earnings calls, BD representatives, including the Individual Defendants, regularly spoke about Alaris's central role in driving BD's growth.

108. For example, on a January 3, 2019 investment analyst conference call, a research analyst from Goldman Sachs asked Defendant Forlenza, "tell us a little bit about in the pump business, kind of where you are from a competitive standpoint?" In response, Forlenza stated "[w]e're doing quite well in the pump business," going on to emphasize that Alaris was "adding to our momentum," and had done "exceptionally well." He also stated that Alaris was integral to a suite of other "interoperab[le]" BD products, thereby further driving Alaris revenue:

> That is—and that is ***adding to our momentum***. You saw that momentum in the fourth quarter in that business, both pumps and the cabinetry on the dispensing side did well, but the pumps did ***exceptionally well***. But ***bigger driver*** [sic] ***is the connectivity, the interoperability*** side of this with the pharmacy and all the workflow and safety improvements that you're getting out of that. So, in 2018, we continue to gain share, expect that, ***that business will continue to do quite well in 2019***. As the interoperability part is now part of the bigger health site, informatics that we have over the entire system, including the pharmacy, the compounding, the pumps, the cabinetry and all of that. So as we build that complete system, the ***pumps are a vital part of that***. So doing quite well.

109. At BD's Annual Shareholders Meeting on January 22, 2019, Forlenza asserted that Alaris was "continuing to fuel growth" for BD, along with BD's interoperable Pyxis and HealthSight products.

110. During BD's earnings call for the first quarter of FY19, held February 5, 2019, Forlenza again highlighted Alaris, stating "on the Medical side, we're expecting continued strong growth in MMS as we do well, both in dispensing, but in—***particularly on the pump side of things***." Alberto Mas, BD's EVP and President of the Medical segment, added: "On the infusion side, we're seeing continued above-market growth. . . . A lot of that has to do with great acceptance of our refreshed Alaris M2 pump."

111. On August 6, 2019, BD held its FY19 third quarter earnings call, during which Polen touted the MMS business, noting the "really strong number in MMS this quarter as well, which is reflecting the continued momentum that we see in that business." Mas elaborated,

explaining that "the drivers are the ones that we had mentioned in the past in terms of our core platforms in [Q]2, Alaris, Pyxis ES."

112. On September 4, 2019, at a Wells Fargo Healthcare Conference, Polen responded to an analyst question about "drivers" of BD's recent strong financial performance by stating that "the vast majority of that came from U.S. MMS infusion pump business [i.e., Alaris], where we saw that business grow mid-teens."

113. Underscoring Alaris's importance to BD's earnings, investment analysts covering the Company regularly zeroed-in on Alaris performance in their questions to BD executives during calls and conferences, and in their reports to investors. Analysts' statements reflected that investors accepted and adopted BD's representations about Alaris's importance to BD's revenues, and the expected continued growth in Alaris-related revenue for BD Medical and the Company.

114. For example, on February 5, 2019, analysts from Evercore ISI reported to investors that market share gains for BD Medical's MMS unit were "driven by Alaris pumps." Analysts from BMO reported to investors that "Medical Management Solutions (up 6.7%) was driven by … placement of infusion sets," and noted "category share gain, including 200 bps for infusion sets (Alaris)." (Internal emphasis and quotation marks in original omitted.).

115. At a Barclays Global Healthcare Conference on March 12, 2019, an analyst from Barclays Bank PLC asked Defendant Polen: "[T]his has been a business that has actually overdelivered … and last year, it had a really strong level of growth and even continuing it into the most recent quarter. How should we just think about the profile for Pyxis and the Alaris business going forward?" Polen's lengthy response emphasized that BD was "still … very, very passionate about our vision that we painted at the time of the CareFusion acquisition."

116. On May 9, 2019, an analyst report from BMO Capital Markets informed investors that "BD Medical sales" were up 3.8% compared to the prior quarter, and MMS was up 7.3%, "driven by strength in infusion systems . . . ."

117. At a June 13, 2019 Goldman Sachs Global Healthcare Conference, an analyst commented in a question to a BD representative: "You've seen tremendous share momentum here with Pyxis and pumps."

118. On August 6, 2019, an analyst report from J.P.Morgan informed investors that, within BD Medical, "Medication Management was the standout once again, as the company continued to gain share with the Alaris and Pyxis systems."

119. Days before the Class Period, investment analysts covering the Company continued to broadly accept Defendants' representations about Alaris driving revenue growth for BD. For example, in an equity research report on BD dated November 1, 2019, analysts at Cowen identified to investors "continued momentum and share gains from Alaris infusion pumps and Pyxis ES" as a "tailwind" for the business that supported a projection of annual revenue growing to well over $9 billion in the BD Medical segment.

120. Similarly, in an equity research report dated November 4, 2019 (the day before the Class Period began), investment analysts from Zacks highlighted for investors "BD's Alaris Pump" as one of the products that "***continue to drive the company***."

121. In sum, through numerous statements to the market leading up to the beginning of the Class Period, Defendants clearly articulated the importance of Alaris to BD's growth and revenues, and created an expectation that Alaris's growth would continue unabated. Thus, significant information relevant to the risk that Alaris revenues and its anticipated growing market share could be compromised was highly material to investors.

C. The Undisclosed State of Affairs at BD with Respect to Acute Alaris Device and Regulatory Issues, Before and During the Class Period

1. BD's Private 2019 Meetings with the FDA Regarding Alaris that Resulted in the Ship Hold

122. While Defendants portrayed Alaris as a dependable engine of BD revenues and growth, and investment analysts accepted and repeated their claims, by the late summer and early fall of 2019—unknown to investors—regulatory and quality issues with the device were coming to a head that would cause Alaris to be withdrawn from the market indefinitely.

123. Indeed, numerous FE accounts, based on direct knowledge of relevant events, confirm that the Alaris ship hold that Defendants announced to the market on November 5, 2019 was prompted and driven by the Pre-Class Period FDA Meetings—non-public meetings and exchanges BD had with the FDA in the several weeks just prior to that date.

124. FE-6 was one of the lead representatives on behalf of BD in the FDA meetings and communications in question. According to FE-6, participants in the meetings and communications on behalf of BD included: Keith Mclain (BD's Global Head of Quality for MMS), Jessica Smith (BD's Global Head of Regulatory Affairs for MMS), Bhupesh Mahendru (Head of Quality for the Infusion Division of MMS), and Michelle Badal (VP of Regulatory Compliance in the Quality function at MMS).

125. FE-9 was informed by his direct supervisor, Mahendru, that Mclain, Mahendru and others participated on behalf of BD in several meetings and communications with the FDA in late summer and early fall of 2019.

126. FE-10 was informed by his direct supervisor, Badal, that she participated in meetings with the FDA about Alaris issues before, during and after the imposition of the ship hold in November 2019, on behalf of BD. FE-10 said Badal was "very up front" with FE-10 and

his colleagues about her participation in these meetings with the FDA. FE-10 was informed by Badal that Mclain and Mahendru also participated in the meetings on behalf of BD.

a. Initial FDA Meeting Regarding Alaris Issues

127. The series of meetings started in approximately August 2019, when the FDA approached BD, according to FE-6. The FDA had recently identified an issue and recall with another pump manufacturer, Fresenius Kabi USA ("Fresenius"), related to a "Keep Vein Open" ("KVO") battery alarm. FE-6 reported that, as a consequence of that recall and because BD was the predominant infusion pump company with roughly 70% of the market, the FDA approached BD. The FDA interacted directly with FE-6, and asked questions about Alaris to determine if there were similar KVO issues with that device.

128. FE-9 similarly reports that in the summer of 2019, following an investigation by the FDA of a BD competitor whose infusion pump suffered from certain alarm problems, the FDA questioned BD about any similar alarm issues Alaris may have.

129. Corroborating FE-6's and FE-9's accounts, in or around June 2019, infusion pump manufacturer Fresenius issued a voluntary recall of its infusion pump following a software failure that caused a KVO alarm to malfunction. The FDA classified the recall as Class I on August 12, 2019, explaining that the software failure could result in under-infusion or over-infusion, which could lead to death or serious injury. In August of 2019, the FDA publicly stated that "KVO alarms should be high priority."

130. FE-6 reports that, in response to the FDA's request, BD collected and provided information on Alaris alarms to the FDA, which the FDA reviewed. The FDA stated to BD, upon review of the information BD supplied, that certain things within the Alaris alarms were not correct, and needed to be fixed.

131. Similarly, FE-9 was informed by Mahendru that the FDA became "frustrated" with BD's responses to its inquiries about Alaris alarms. The FDA called for a larger meeting with BD management to find out "what was going on" with Alaris. FE-9 reports that this meeting occurred in late summer/early fall 2019.

b. Subsequent FDA Meeting regarding Alaris Issues

132. In September or October of 2019, FE-6 confirms that he and others from BD met with the FDA again. According to FE-6, the primary speakers in the meeting for BD were Mclain, Mahendru, Jessica Smith and Badal. The meeting was held in a conference room in San Diego, with several people from BD (including technical specialists) and approximately four to five people on a conference line from the FDA in Washington, D.C.

133. According to FE-6, in the meeting, BD's representatives discussed not only: (i) the specific alarm issue the FDA had first raised; but (ii) changes and fixes that had already been made to the Alaris software; and also (iii) additional "anomalies" and issues—and additional software fixes that were needed to address those. Mclain presented several Alaris issues in the meeting.

134. One longstanding Alaris issue that the FDA and BD specifically discussed in the meeting was the unresolved LBA issue that had been flagged in the Form 483 the FDA issued to BD in September 2018. *See also* paragraphs 97-99.

135. According to FE-6, after BD had identified the various Alaris issues, the response from the FDA was that the set of software issues was "concerning," and the FDA stated to Mahendru and the other BD representatives: "[Y]ou should have been fixing these issues. You should do a 510(k). We don't think you should be shipping this product with these issues."

136. FE-6 reports that "as soon as" the FDA said it had concerns with the software and told BD it should not be shipping the device, and that it should have been fixing these issues and

clearing them in a 510(k), the product was put on ship hold. The decision, made by Mahendru and Mclain, took "less than an hour or two" after the FDA meeting concluded. According to FE-6, the FDA "was the impetus for the ship hold" BD announced in November 2019.

137. Several FE reports corroborate this account.

138. FE-9 reports that Mahendru informed him that in an early fall meeting with the FDA, BD had put on a presentation to fully brief the FDA on not only the alarm issue the agency had originally raised, but also on the LBA issue and other issues with Alaris that BD had been working on. Mclain, Mahendru and others participated in that meeting for BD. FE-9 reports that Mahendru told him that the FDA asked BD's representatives what would be involved in fixing the identified issues, and BD responded that it would require approximately nine months of work. In other words, remedying the safety issues and defects that the FDA had identified would require nine months of work on Alaris software before BD could even prepare and file a 510(k).

139. Mahendru told FE-9 that BD's responses in this "big meeting with the FDA" about the Alaris issues "were unacceptable to the FDA" and that the FDA "directed" and "dictated" that the ship hold be imposed. Following that meeting with the FDA, Alaris was placed on a ship hold.

140. FE-10 reports that Badal regularly informed him and his colleagues about meetings in and around November 2019 with the FDA in which Badal was participating on behalf of BD, and that Badal informed him that the FDA "had placed a freeze" on shipping Alaris.

141. In the course of working on Alaris pump issues, FE-11 worked and communicated with MMS Quality team members. FE-11 learned from Quality team members

that the FDA told BD in the fall of 2019 in connection with the ship hold that it was requiring a new 510(k) for Alaris.

142. FE-3 learned in 2019, before the Class Period, that there were numerous "trackers" concerning "bugs" or defects in Alaris products that required BD's attention. He explained that these trackers were old—some had existed for eight years or more. FE-3 understood that when the FDA learned of these trackers in 2019, Alaris product shipments were put on hold by no later than October 31, 2019. FE-3's Director told him on October 31, 2019, that BD was going to put a ship hold on Alaris.

143. FE-5 likewise reported that the Alaris ship hold that BD announced in November 2019 related to both the LBA issue and also a large number of software anomalies (also referred to within BD as "bugs" or "trackers") that BD knew were present in the device. FE-5 explained, based on personal experience working with the documents, that BD compiled "software anomaly reports," also referred to as "Issue Tracking Memos," that listed known or reported software problems with its devices, including Alaris, noting details about the error and whether it was associated with patient harm. FE-5 recalled that, in 2016, the software anomaly report for Alaris (which he personally reviewed) included around 200 known anomalies, including some anomalies associated with patient risk and harm. FE-5 reported from personal knowledge that, by May of 2019, the Issue Tracking Memo related to Alaris was eighty-seven pages long. In the fall of 2019, Alaris still was associated with a host of software anomalies, many of which had not been corrected in years. FE-5 learned in discussions with colleagues in Regulatory Affairs and through his continuous work on Alaris regulatory issues in the MMS group responsible for Alaris that the FDA learned of the numerous software anomalies related to Alaris in 2019, and that both these anomalies and the LBA issue were factors "contributing to" or underlying the Alaris ship

hold BD announced in November 2019. FE-5 also stated based on personal knowledge from working extensively on Alaris regulatory projects in 2019 and 2020 that the unresolved LBA issue was "part of the ship hold" on Alaris that BD disclosed to the public on November 5, 2019.

144. FE-7 reports that he learned in discussions with his supervisor and colleagues that the FDA had multiple discussions with BD representatives, including Mclain, in the summer and early fall of 2019 regarding problems with the Alaris pump. He was informed in "September or October" 2019 that the identified problems were serious enough to stop making the product, and that the FDA's position was that a ship hold should be placed on Alaris at that time. Shortly thereafter, FE-7 learned that Alaris was on a ship hold.

145. FE-6 reports that "upper management layers" at BD were informed of the meetings with the FDA concerning Alaris and the ship hold "at every step of the way." FE-6 was personally involved in reporting up and out about the meetings and outcomes. He further reports that, when the FDA meeting and decision to impose the ship hold occurred in fall 2019, BD Medical Quality Head Shkolnik, Chief Quality Officer Boisier, MMS Business Head Banerjee, "all senior leaders of the business units, and the corporate leaders" all were made aware of what had happened. He states, based on personal knowledge and involvement, "the decision was given to Shkolnik, the Chief Quality Officer [Boisier,] and up to the CEO [i.e., in fall 2019, Defendant Forlenza]." He notes: "Everyone was involved" and made aware. FE-6 also states that within a short period of time, people "throughout the business knew what was happening." According to FE-6, he informed Banerjee, who informed Alberto Mas, who informed then-President and COO, Defendant Polen. Although FE-6 does not know the precise date Polen was informed about the FDA meetings and ship hold, he states that Polen was

informed before the ship hold was announced and before Polen publicly discussed it on November 5, 2019.

2. BD's Prior Knowledge that the LBA Remediation Would Require 510(k) Clearance

146. Before the FDA stated its position in early fall 2019 that the necessary Alaris fixes would require 510(k) clearance, BD itself had acknowledged to the FDA that certain required fixes to Alaris, including the LBA fix, would require a 510(k). BD had communicated as much to the FDA at least twice in the prior year, 2018.

a. BD Privately Acknowledged to the FDA That the Fix for the LBA Issue Would Require a 510(k) in its Response to the Non-Public September 2018 Form 483

147. In late 2018, in connection with the Form 483 the FDA issued to BD concerning the unresolved LBA issue, BD acknowledged to the FDA that the fix needed for the LBA issue would require 510(k) clearance.

148. In particular, based on having personally reviewed the underlying documentation, FE-5 reports that the FDA inspected BD's San Diego facility where Alaris is developed, tested, and manufactured from July to September 2018. At its conclusion, the FDA issued a Form 483 to BD for deficiencies identified during the inspection with respect to Alaris-related quality systems and product problems. This Form 483 identified deficiencies and failures related to the Alaris LBA issue that had been the subject of BD's 2016-2017 recall. According to FE-5, the Form 483 noted that "the problem had not been fixed" through steps taken in connection with the recall, and was continuing to drive instances and reports of LBA failures and related issues by Alaris customers.

149. According to FE-5, who reviewed the Form 483, BD's responses and other documents in question, BD provided written responses to the FDA regarding this 2018 Form

483. In a written response BD submitted to the FDA in September 2018, BD stated that BD had determined that 510(k) clearance was required for a software fix that was necessary to correct the LBA issue. By the time of the Class Period, BD had not released that software-based LBA fix nor obtained the needed 510(k) clearance. None of this was disclosed to investors.

150. Similarly, FE-6 states that "later in 2018" the FDA inspected BD's San Diego facility and issued a Form 483 focused on "the continued issue with the Alaris low battery alarm." FE-6 states that he was a member of BD's team that interacted with the FDA around that inspection and Form 483. According to FE-6, the FDA observed that the Alaris LBA issue had not been fixed or solved and continued to receive complaints from the field. Keith Mclain's Quality group in MMS was responsible for determining what to do to try to fix the LBA issue.

151. As an immediate step, FE-6 reports that BD gave customers a "work around" for the issue: it told them to throw out Alaris batteries after two years.

152. But BD wanted to actually correct the LBA software problem, not just offer work arounds. According to FE-6, BD and Mclain wanted to submit a 510(k) to fully remedy the software issue through an algorithm change.

153. FE-6 reports that in its responses to the FDA in late 2018 after receiving the Form 483, BD acknowledged to the FDA that the software changes needed to actually correct the LBA issue would have to be submitted for 510(k) clearance.

154. According to FE-6, BD had also acknowledged to the FDA that the LBA remediation would require 510(k) clearance at least one other time in 2018.

b. BD Submitted a Non-Public 510(k) Application to the FDA Covering a Fix for the LBA Issue in the Failed "Project Monterey" Submission in 2017-2018

155. The prior time had been in connection with a failed 510(k) submission dubbed "Project Monterey," which BD had withdrawn in 2018.

156. FE-6 personally worked on the Project Monterey submission to the FDA and has direct personal knowledge of BD's interactions with the FDA surrounding it.

157. According to FE-6, under this project, in 2017, BD submitted a 510(k) application to the FDA for changes to Alaris to correct several software issues, including the LBA issue that had been the subject of the 2016-2017 recall.

158. FE-6 reports that the FDA provided preliminary feedback to BD about its 510(k) application for the LBA and other issues, prior to making its substantive review and formal decision. The FDA told BD that its documentation related to the submission was incomplete and insufficient. As a result, prior to the FDA's substantive review, and in order to avoid a negative formal determination by the FDA, BD withdrew the Project Monterey application in 2018.

159. Corroborating FE-6's report, FE-5 also personally worked on Project Monterey in 2017-2018. FE-5 reports that, in November 2017, BD submitted a 510(k) application to the FDA for the Alaris changes entailed in Project Monterey.

160. According to FE-5, in the course of the application process, the FDA made clear to BD that, in order to provide the requested 510(k) clearance, it needed additional answers, documentation and data, including related to substantive revisions that had already been made to the device. For example, the FDA wanted to see additional full test reports for Alaris features and software versions that had been changed and specifically asked BD why software changes in versions 9.15, 9.17, and 9.33 did not require 510(k) clearance. FE-5 further recalled that the 510(k) application included a table that was required to be filled out with information on

historical changes made to Alaris, but in several instances, the Company had simply left blank entries where explanations as to why those changes did not require a 510(k) were called-for.[3]

161. According to FE-5, the FDA's request for additional supporting information and documentation for the 510(k) application "presented a problem" because BD could not respond adequately. BD did not have the documentation and data that the FDA had flagged and requested.

162. FE-5 recalled that BD was preliminarily informed in or around April 2018 that, given these deficiencies and missing information, the FDA was not going to accept the Project Monterey 510(k) application. Consequently, BD withdrew the 510(k) application by approximately June 2018.

163. That BD had tried—and failed—to gain 510(k) approval for fixes to the persistent LBA issue, and for Project Monterey generally, was not disclosed to the public.

164. According to FE-5, based on personal knowledge from performing related work, Defendant Polen directed an analysis of why the Alaris 510(k) submission under Project Monterey had failed in the months following BD's June 2018 withdrawal of the submission. Polen received reports detailing the application and the reasons why it had failed. Polen thus knew that BD had sought 510(k) clearance for changes needed to correct the Alaris LBA issue, and that the clearance had not been obtained nor the LBA remediation made.

165. Thus, in connection with both the Form 483 BD received in September 2018, and the failed Project Monterey application that BD withdrew in mid-2018, BD had expressly

[3] FE-2 recalled meetings he attended prior to leaving BD Medical's MMS unit in early 2019 led by Global Head of Quality Keith Mclain at which the need to obtain 510(k) approval for a backlog of software changes BD had made to Alaris was discussed.

acknowledged to the FDA that 510(k) clearance was necessary for the fix required to remediate the Alaris LBA issue. The public was not aware of either event.

166. In addition, prior to imposing the ship hold, BD was once again taking steps towards seeking 510(k) clearance for an LBA fix in 2019. In and around October 2019, FE-5 reports that he personally conducted a regulatory assessment regarding Alaris software changes that related to the LBA issue, at the direction of Heather Jalisi, Director of Regulatory Affairs in the MMS unit. According to FE-5, the purpose of the assessment was to support an anticipated 510(k) application that would include the needed software fix for the persistent Alaris LBA issue. The assessment project included personnel from the Quality and Regulatory Affairs functions, specifically BD Regulatory personnel and Quality Engineers, as well as Software Engineering Manager Andreas Krueger and various software engineers working for BD. FE-5 reported that despite the prior "half-ass" recall for the low battery alarm issue, BD still had not fixed the LBA problem as of October 2019.

167. FE-8 attended a meeting in "January or February of 2020" in which Defendant Polen and Amy Simunovich, Head of Regulatory Affairs for BD Medical, came to MMS in San Diego and discussed the Alaris ship hold and 510(k) filing. Simunovich discussed the needed Alaris 510(k) and the amount of work it would take to get it off the ship hold. Simunovich predicted that the 510(k) would take approximately twenty-four months to obtain from the FDA.

c. BD's Continuing Shoddy Device Documentation for Alaris Recognized Internally by October 2019

168. Similar to the device history documentation deficiencies that had torpedoed the Project Monterey 510(k) application, Former Employees who assessed BD's Alaris files in regulatory reviews in the latter half of 2019 report inadequate documents that would present an additional issue if BD sought a 510(k) clearance for Alaris again. The Alaris files and

documentation issues would compound the challenge of the already onerous 510(k) submission preparation process.

169. In the course of FE-5's LBA-related review in October 2019, which he undertook alongside BD Quality Engineer Jorge Espinoza, FE-5 found "shoddy" testing documentation in Alaris design and development files. The issue was escalated to Keith Mclain, Global Head of Quality in MMS, and Bhupesh Mahendru, Head of Quality for the Infusion unit.

170. Similarly, FE-4 worked at BD from mid-to-late 2019 as a Quality Assurance Manager with a primary responsibility of conducting reviews of quality systems at several Alaris production facilities. FE-4 explained he was specifically hired in mid-2019 to help BD prepare for an anticipated FDA inspection. FE-4 explained that BD was supposed to maintain documents illustrating that the production of Alaris pumps was being done in a uniform fashion and in accordance with regulatory requirements.

171. Overall, FE-4 stated that BD's records were a mess, with many missing. His review of Alaris files uncovered numerous document deficiencies, including many instances of missing records that would need remediation. According to FE-4, there were instances in which the pump was modified as the result of a defect or other issue and the records were incomplete—or even completely absent.

172. To this end, FE-4 specifically reviewed Alaris records dating back to the pumps' original design, including the "Design History File" mandated under the FDA's Quality System Regulation. He stated that the lack of documentation for the Alaris Design History File was particularly troublesome. To conduct a review of quality management processes and quality systems, FE-4 stated he would focus on documents the FDA might look at to determine what documents were missing or would need to be remediated. He explained that if there was an issue

with the product, the first thing one does is look to the original design to make sure the parts were all in specification. Without the design history file, this was not possible.

173. FE-4 further explained that two separate "GAP Analysis Reports" were prepared following the review (he was personally involved in their preparation). The first specifically addressed whether the three Alaris production facilities followed the same standard practices and sought to ensure that they were all in compliance with accepted International Organization for Standardization. FE-4 explained the report identified gaps in compliance and uniformity in the three facilities and recommended corrective action. FE-4 stated the second GAP Analysis Report analyzed the gaps in the record-keeping related to problems and modifications made to Alaris pumps over time. This report was created to reflect the extent of the missing and lost documentation. FE-4 recalled many instances in which proper documentation simply was not available in order for him to determine what the issue was, or if the appropriate remediation efforts were adopted for each event.

174. FE-5 also encountered numerous problems and deficiencies in Alaris device files when he performed other regulatory assessments related to the device in 2019 and 2020.

175. Specifically, FE-5 reported that, on or around November 11, 2019, the entire BD Regulatory Affairs department was called into a meeting. In that meeting, which FE-5 attended, the team was told to devote 70% of their time going forward to regulatory assessments on all changes, or "change orders," that BD had made to Alaris in the past five years, and that the FDA had called for this comprehensive Alaris review in a recent communication to BD. The resulting review of Alaris changes continued from November 2019 to at least August 2020.

176. FE-5 performed regulatory assessments in 2019 and 2020 as a part of this broad review. In some instances, FE-5 and his colleagues could not trace changes that had been made

to Alaris because BD's documents related to the device, including change orders and related Alaris files, lacked information or stated that actions had occurred or changes had been made when they plainly had not. Documents in the Alaris files lacked product-related information that they were required to contain. According to FE-5, in some cases, "you couldn't tell" from the Alaris files what had been changed in the device.

3. BD's Unauthorized Move to Lift the Ship Hold before Christmas 2019 and the FDA's Rejection of the Move

177. After BD imposed the ship hold and Reidy and Polen announced it in public statements on November 5, 2019, FE-10 recalls Badal stating to him and some colleagues that BD was losing a "boatload" of money as a result of the ship hold.

a. The FDA Confirms the Ship Hold Is in Place

178. FE-6 reports that the FDA met with Mclain and other BD representatives about Alaris a few weeks after the ship hold began, in roughly December of 2019. FE-6 personally participated in this meeting. The FDA asked BD to confirm whether it was shipping Alaris. Mclain responded that BD was not (which, at the time, was true). FE-6 reports that the FDA's response was approving—to the effect of: "Good."

179. Similarly, FE-5 states that in a "pre-submission" (or "pre-sub") communication BD had with the FDA concerning issues related to Alaris software changes in the winter of 2019-2020, the FDA asked BD to confirm that Alaris "was on a ship-hold," and BD confirmed that it was. The ship hold announced in November 2019 was in fact in place at the time.

b. BD Then Unilaterally Lifts the Ship Hold after Correcting Certain Anomalies, but Not the More Significant Issues Including the LBA Defect, Nor Seeking a 510(k)—and without the FDA Knowing

180. According to FE-6, after the ship hold was imposed, BD, through the MMS Quality team, endeavored to determine which of the Alaris issues and anomalies "needed a

510(k)" and which potentially did not. The MMS unit Quality function, working with the R&D function, worked in November and December 2019 to resolve any anomalies in Alaris that it could, while leaving aside the larger, "more significant" defects, such as the LBA issue, that the FDA had identified and that required 510(k) clearance.

181. Meanwhile, according to FE-6, a 510(k) submission "package" for the identified Alaris problems, including the LBA issue, was being prepared in and after November 2019. The 510(k) submission requires a voluminous set of materials that includes testing, verification, validation and risk assessments, and a substantial amount of this work was being done in this time period. Though the work was underway, it was not completed. Luchy Roteliuk, VP of R&D in the MMS R&D function, was heavily involved in the ongoing 510(k) preparations.

182. FE-8 similarly reports that BD's preparations for an Alaris 510(k) were underway but not complete in this time period. FE-8's direct supervisor, Katie Walton, had a lead role on the Alaris 510(k) preparation and strategy, along with Mark O'Donnell. FE-8 reports seeing whiteboards in Katie Walton's office detailing ongoing Alaris 510(k) plans and work in January 2020, just after the holidays.

183. FE-7 similarly reports that, after the ship hold was in place, the focus of the MMS R&D group "completely changed." His group was ordered to work on a specific list of fixes for Alaris anomalies. By approximately mid-December 2019, all of the selected "safety fixes" were complete. FE-7 believes that the safety issues that were not addressed at that time were "skipped to avoid having to file a 510(k) with the FDA."

184. FE-6 reports that just before Christmas in December 2019, BD implemented certain software changes. (This fact is corroborated by Defendant Polen's statement to investors on February 6, 2020, that "we released that software improvement in December"). FE-6 was

personally directly involved in the decision to implement these changes. The software changes did not correct the LBA issue or other significant issues BD knew would require 510(k) clearance. Those issues were left un-remediated. The fixes implemented included "minor ones."

185. According to FE-6, after implementing these changes, BD lifted the ship hold. FE-6 was personally involved in the decision. BD had not consulted the FDA before doing so.

186. Similarly, according to FE-5, just after the meeting in which FDA confirmed that Alaris was not shipping, BD worked fast "over a weekend" to implement several software changes to Alaris that addressed some—but not all—of the software anomalies identified to the FDA. Just after it implemented those software changes, BD unilaterally resumed shipments.

c. Within Weeks, the FDA Learns That BD Has Unilaterally Lifted the Ship Hold and Rejects the Move, and BD Reinstates the Ship Hold

187. FE-5 reports that BD's lifting of the Alaris ship hold in December 2019 (which Defendants discussed with investors no later than January 2020) was not authorized by the FDA, and was not accepted by the FDA.

188. According to FE-5, the FDA was "completely caught off guard" that BD had released the ship hold and did not accept that the release of the ship hold was appropriate. FE-5 described the FDA's reaction upon learning of BD's move as "You did what?!" As a consequence, BD was obligated to resume the Alaris ship hold, which it did in or around January 2020.

189. FE-8 reports that when the FDA learned in meetings in January 2020 that BD had resumed shipping Alaris, the FDA was "forceful" in its response to BD, leaving no other option for BD but to go back on ship hold "immediately, or face the wrath of FDA and the Justice Department." FE-8 reports that participants for BD in the meetings in question with the FDA included Mclain, Mahendru, Badal and Mark O'Donnell. FE-8 was informed about the

discussions by his supervisor Katie Walton, who was informed by O'Donnell, with whom she worked closely on Alaris 510(k) preparations.

190. Similarly, FE-6 reports that approximately three weeks after BD unilaterally lifted the ship hold, Mclain, Mahendru and four or five other BD representatives were on a call with the FDA. FE-6 participated on the call on behalf of BD. According to FE-6, the FDA was informed that BD had resumed shipping Alaris. The FDA expressed disappointment, questioned BD's representatives and heard their rationale. The FDA swiftly rejected BD's rationale, and re-affirmed its prior position, stating that BD needed to obtain a 510(k) for the required Alaris changes, including the changes in question that BD had just made.[4] FE-6 reports that BD immediately put the ship hold back in place (FE-6 was personally involved in that process, decision and action by BD).

191. According to FE-6, the resumption of the ship hold was again "reported up the chain of command through senior management within an hour or so." FE-6 states that the report of events "quickly went to everyone."

* * *

192. Thus, when Defendants spoke to the market about the ship hold and the supposed reasons therefor on November 5, 2019 and discussed it thereafter during the Class Period, Defendants knew that the hold was driven by the FDA stating Alaris should not be shipping because of numerous device issues. Defendants also knew that the FDA had said that Alaris would need a new 510(k). Preparations for an Alaris 510(k) were underway at BD, but the submission was not ready: the set of device fixes would require months of work and the full package of testing data and other materials was not complete. FDA review, once the package

[4] FE-1 noted that in general, if the FDA did not provide 510(k) clearance for a change to Alaris, the pump could not ship with the feature.

was submitted, would itself entail several months, at a minimum. As FE-6 put it, BD was "damned if you do, damned if you don't"—BD "had tried the 510(k) for the low battery alarm and other issues [in the Project Monterey application] and didn't do a good job, and had insufficient documentation, and had to withdraw it. We wanted to fix the software and had R&D developing fixes on a lot of these issues, but the obstacle was getting 510(k) clearance from the FDA to bring the fixes to market." That would take an indefinite amount of time, during which Alaris could not be sold.

D. The Class Period: Defendants Mislead Investors about BD's Performance Prospects, Reliant on Alaris Sales, by Misrepresenting Severe Product and Regulatory Issues That Had Necessitated the Alaris Ship Hold

193. As detailed below, Defendants made numerous Class Period statements regarding the ship hold, related Alaris matters and BD's FY20 Guidance that were rendered false and misleading by the omission of material undisclosed facts regarding the device and regulatory issues that were already keeping Alaris from the market.

194. In these statements, Defendants: (i) described the ship hold as a brief Q1 pause for upgrades like those BD routinely made in the ordinary course; (ii) touted Alaris as a revenue driver that would help BD deliver its robust FY20 Guidance; and (iii) described discussions with the FDA as concerning mere implementation and timing matters—keeping from investors that the true state of affairs was far worse. In fact, Alaris was not being shipped because the FDA had expressly stated to BD that the product should not be shipping, after learning of myriad Alaris software issues. There was no near-term resolution in sight for the problem: BD knew needed fixes would necessitate 510(k) clearance, and had acknowledged as much to the FDA. But obtaining such clearance involved complex submissions and a challenging review process (as Defendants well knew from the failed Project Monterey attempt in 2018), for which BD was not yet prepared. As a result, Alaris's return to market at all in FY20 was imperiled, and the

notion that it could drive revenue growth for BD in the second-through-fourth quarters of FY20 had no reasonable basis.

195. When Defendants, on and after November 5, 2019, provided investors with what appeared to be extensive detail about the Alaris ship hold, related FDA discussions, and Alaris's expected quick return to BD's FY20 revenue mix, they knew or had access to these true facts, but left them out, providing a materially incomplete and misleading picture to the market about these matters.

1. Defendants Tell Investors That Alaris Revenue Will Be Briefly Delayed As Mundane Software "Upgrades" Are Completed During Q1 FY20, and Issue Ambitious FY20 Guidance Based on Alaris's Swift Return to Market

196. Defendants' first materially false or misleading statements to the public markets at issue came on November 5, 2019, when, during a quarterly earnings call for the fourth quarter and full year of FY19 BD: (i) announced the Alaris ship hold; and (ii) announced its full FY19 earnings and issued FY20 Guidance.

197. In announcing BD's FY19 results, Defendant Reidy highlighted the now long-established theme of MMS unit market share gains driving BD Medical growth. Reidy stated: "BD Medical revenues grew 5.3% in the fourth quarter and 5.1% for the full fiscal year. As expected, fourth quarter performance in the Medical segment was driven by ongoing momentum and share gains in Medication Management Solutions [MMS] and continued strength in Pharmaceutical Systems."

198. Defendants Forlenza and Reidy then announced BD's FY20 Guidance, which included revenue growth of 5% to 5.5% and earnings per share between $12.50 and $12.65. Focusing investors' attention specifically on BD Medical, Reidy added that the Company was forecasting strong revenue growth of 4% to 5% in that segment alone.

199. In next announcing the ship hold, Reidy began by discussing its revenue impacts. He told investors that BD's overall revenue growth would be approximately 1% lower in the first half of FY20 than the full fiscal year's revenue growth of 5% to 5.5%, and that the first half's lower guidance resulted from expected "first quarter revenue growth of 1% to 2%." That slow Q1 growth, Reidy explained, was due to a temporary delay in Alaris shipments—i.e., the ship hold. Adding purported detail, Reidy explained to investors that the ship hold was being done to allow BD to implement "***improvements***" and "***upgrades***" to Alaris software during the first quarter of FY20.

200. Reidy assured investors that the Alaris ship hold would simply "***move the timing of some sales from Q1 to the balance of the fiscal year***." After this temporary delay in Alaris shipments, he claimed, Alaris sales would resume, allowing BD to meet its FY20 Guidance.

201. Providing supposed detail on BD's interactions with the FDA concerning the ship hold, Reidy went on to explain that BD was engaged in discussions with the FDA regarding implementation questions: "***We are in discussions with the FDA about the timing of implementation of these upgrades and the possibility of bundling them with a new software version release.***"

202. Keen to understand more about the revenue implications and nature of the ship hold, an investment analyst on the earnings call, Vijay Muniyappa Kumar of Evercore ISI, asked Reidy to provide more detail on "the Q1 impact on MMS" and for "some color on what's changing there" with respect to the "software rollout." In response, Defendant Polen reminded investors that Alaris was the "clear leader and product choice" in the infusion pump market, before representing that "***it's part of our process and our strategy in the business to continually iterate and make enhancements to the platform. . . . And this upgrade right here is a continued***

reflection on those investments." Polen also emphasized the "record levels of continued share gain" in the infusion business, and represented to investors that, currently, "***we see no slowdown in that momentum***":

> As you know, Alaris is the clear leader and product choice in, not only the infusion market, but also as part of a broader Medication Management Solution that our customers are investing in. And ***it's part of our process and our strategy in the business to continually iterate and make enhancements to the platform***. And so you've seen us do that certainly on the hardware side with significant investments, such as the new Alaris M2 pump launch, which has been extremely well received by our customers. ***And we've been making those same type of investments in software upgrades over the last couple of years. And this upgrade right here is a continued reflection on those investments and will be forthcoming.***
>
> I would just say in terms of momentum, maybe just one other comment there on your question, we saw in FY '19 near or at, I'd say, record levels of continued share gain both in the infusion and the dispensing business, so about 200 basis points of gain in infusion and 100 in dispensing. And ***we see no slowdown in that momentum***.

203. Analysts and market commentators covering BD had not expected the news concerning deferred Alaris shipments and revenue, but they broadly accepted Defendants' representations about: (i) the reasons for the temporary ship hold; and (ii) Alaris's strong "share gain" prospects in FY20, after the Alaris "improvements" and "upgrades" were completed in Q1 FY20. As a result, analysts expressed assurance about BD's ability to deliver the FY20 Guidance.

204. For example, in a November 5, 2019 report to investors, investment analysts at J.P.Morgan wrote that the "initial top-line guidance of 5.0-5.5%cc [constant currency] [w]as a conservative baseline for the company" and that:

> [M]anagement is pointing towards F1H revenue growth 100bps below the full-year range and F1Q growth of only 1-2%cc as the company implements improvements to the Alaris pump that will move sales from F1Q to the balance of the year. This implies F2Q growth of ~5.5% or so, and 2H growth in the range of 6-6.5%cc sales growth.

205. Similarly, in a post-earnings call research report on November 5, 2019, RBC Capital Markets analysts reflected Defendants' story that temporary Alaris revenue delays would be followed by a robust return to drive major growth, stating "[w]e believe that BDX can still grow FY20 revenues ~5%+ y/y, driven by new/upcoming products . . . as well as continued share gains in MMS."

206. Also, in a report to investors on November 5, 2019, investment analysts at UBS repeated Defendants' claims on the earnings call, reporting that in the start of FY20 "Alaris software and features update will adversely impact BDX's topline by 1-2% points. Management expects a catch up through the course of the year."

207. Wells Fargo likewise noted on November 5, 2019 that the sales growth "deceleration" discussed on the call reflected "impact of order timing related to the pending Alaris pump software upgrade." Wells Fargo reiterated Defendants' representations about Alaris shipping delays sliding pump sales into the rest of FY20, noting that "timing of Alaris pump software upgrade[] in the US will push sales into FQ2-FQ4."

208. In their November 5, 2019 report, analysts from William Blair discussed "the impact from a software validation that is being finalized for the company's Alaris pump franchise." Reflecting an impression that the Alaris software changes related to an industry-wide initiative, the analysts wrote: "Importantly, this is not in any way a competitive issue (it pertains to everyone in the space) and ***is not something that should result in lost revenue***."

209. Based on the November 5, 2019 earnings release as well as "additional color" provided by BD executives (including Forlenza, Reidy and Polen) in private meetings on November 6, 2019, a November 14, 2019 J.P.Morgan report to investors discussed "delayed shipments of the Alaris pump that were pushed out to F2Q from F1Q, which is a timing issue

rather than a read-through to underlying demand." J.P.Morgan parroted Defendants' misleading explanation for the delay (and, similar to William Blair, also asserted that a response to an industry-wide FDA initiative was the reason for the ship hold):

> ***On the pump side, we remain bullish on Becton's ability to continue capturing share despite this delay in revenue.*** An FDA initiative to standardize alarm configuration on pumps is the main reason why Becton has postponed the shipment of some orders, as the company would rather upgrade the pumps and then ship them rather than vice versa. With underlying demand and orders stable, we see Becton as well positioned to post another year of share gains in FY20 (200-300bps in FY19) as it continues to boast a superior comprehensive offering within Medication Management. The integration between Alaris and Pyxis (compounding and supply) represents a meaningful value add for hospital systems, and one that competitors continue to lack.

2. Defendants Reaffirm FY20 Guidance and Continue to Mislead Investors Concerning "Temporary" Delays to Alaris Shipments

210. Defendants continued to misrepresent the true state of affairs to investors on November 21, 2019. On that day, during the Company's presentation to analysts at a Jefferies London Healthcare Conference, Defendants reaffirmed FY20 Guidance reliant on Alaris revenue, reiterating that the temporary shipping delays related to "upgrades" would soon abate.

211. At the conference, a Jefferies LLC analyst asked BD to explain "some of the phasing of expectations on a top line perspective." In response, BD's SVP, Treasurer, and CFO of BD Medical, John E. Gallagher, stated that:

> As far as Q1 phasing, we did call out Q1 being a 1% to 2% grower. There are a number of dynamics there that are driving it, which effectively create a bit of an imbalance first half, second half. Meaning with a 1% to 2%, we're expecting the first half to be about 4%, ***the back half to be about 6%***.

212. Indeed, reiterating Polen's and Reidy's points from the November 5, 2019 earnings call, Gallagher highlighted Alaris as among a few "key factors" driving performance, and emphasized that while Alaris shipments and installations were delayed in the first quarter, BD anticipated "getting all of that back inside of the fiscal year":

> One of the larger ones to call out as well is Alaris pumps. We're ***upgrading*** some software. This is in our MMS business, our infusion pumps. ***We're upgrading some software in the pumps, and that will delay some installations and shipment into the subsequent quarters, and we anticipate getting all of that back inside of the fiscal year. So that's what's driving the Q1 being at that 1% to 2%***.

213. Jefferies LLC analyst, Brandon Couillard, probed the FY20 Guidance: "[W]hat parts of the portfolio do you expect to grow faster, slower because -- as you look into '20? What areas do you have the most runway, let's say, for future share gains?" Again, BD's representative emphasized Alaris's critical role in driving BD's growth:

> [W]e've seen very, very strong growth in our Alaris pump business. That -- and although we do see some timing outside of Q1 and into the subsequent quarters of fiscal '20, we posted our strongest ever revenue dollars in the MMS business in the fourth quarter, and ***we expect that momentum to continue when you look at the full year of fiscal '20.***

214. Less than two weeks later, at the Evercore HealthCONx Conference held on December 4, 2019, BD continued to mislead investors as to the strength and prospects of BD's pump business in 2020. Specifically, when Evercore ISI Institutional Equities analyst, Vijay Muniyappa Kumar, asked: "Has anything changed at all in the competitive side for you guys on the pump side," Defendant Reidy replied: "No. Actually, the pump side, we've been taking 200 points of share last year, and ***we see that continuing, and we have some visibility to that.*** So we don't see that being the case."

215. Kumar then queried, "I know you had revenue deferral related to the software chain on the pump side, but that's more of a —," before Defendant Reidy jumped in, assuring: "***That's a timing issue. First half issue, yes***."

216. Even as they minimized the true regulatory and product issues and misleadingly talked up Alaris revenues powering BD's growth prospects, Defendants Forlenza and Polen began cashing in on BD's inflated share price. Indeed, less than two weeks after the Evercore conference, Forlenza and Polen unloaded shares for a $4.3 million and $3.7 million in proceeds,

respectively (Forlenza would unload over fourteen times as much by the end of January). These unusual sales, made while Defendants possessed material non-public information, were not in accord with past practices for these Defendants, as reflected below in Section V.

3. Defendants Misrepresent That Alaris Shipments Have "Fully Resumed" and BD Is "On Track" for FY20 Guidance

217. As Defendants unloaded massive amounts of their BD holdings, they continued to mislead investors about BD's ability to rely on Alaris revenues to meet its ambitious FY20 Guidance.

218. During a JPMorgan Healthcare Conference on January 14, 2020, Defendants reaffirmed the FY20 Guidance and misleadingly sought to dispel investor concern over BD's discussions with the FDA—and particularly, whether there would be further delays to Alaris pump shipments and revenue.

219. Defendant Polen proclaimed unequivocally: "***Fully resumed shipping in the first quarter***. So we're back to shipping in Q1 to the majority of our customers."

220. When Polen was later asked if the Alaris situation had "played out as expected," he responded: "***Exactly as expected***."

221. Polen's representations not only suggested that he was fully informed about the events underlying the ship hold, but also gave the false impression that the issue underlying the software "upgrades" first disclosed on November 5, 2019 was resolved.

222. Market participants were comforted by Polen's misleading statements about the resumption of Alaris sales, and investment analysts reported Polen's assurances that the Company was on track to meet the FY20 Guidance.

223. In a January 15, 2020 report, a J.P.Morgan analyst stated, "the [first quarter] postponement of Alaris pump shipments [was] also in-line with expectations as the company worked to implement standardized alarm configurations."

224. In a January 14, 2020 research note, Evercore ISI reported: "Most notable was that . . . [Polen] blessed BDX's first quarter guidance and said that the company is on track to meet its full-year guide as well."

225. In truth, Defendants' representations about the quick resumption of Alaris sales, BD's talks with the FDA, and its FY20 Guidance were materially false and misleading when made. Indeed, as Defendants' subsequent admissions and FE accounts bear out, the product and regulatory issues that drove the ship hold were nowhere near resolved. Based on a slew of Alaris software defects that threatened patient safety, the FDA had called for a ship hold and a new 510(k), and had not approved BD's unilateral resumption of Alaris sales. The underlying defects were not fixed, and could not be without a new 510(k), which could only be obtained through a lengthy review process. Continued Alaris shipments and sales—and therefore, the FY20 Guidance—were in severe peril. Defendants concealed all this from investors.

226. After these misrepresentations, Forlenza again dumped significant amounts of his personal holdings in BD stock. This time, ***he sold over 90,000 shares for proceeds north of a staggering $25 million*** in a series of unusual and suspicious sales over a five-day period from January 23, 2020 to 28, 2020—just days before the falsity of Defendants' Class Period statements was revealed.

227. On January 28, 2020, BD held its Annual Shareholders Meeting. During the meeting, Defendant Forlenza again re-affirmed FY20 Guidance and stated:

> And since we just closed the books on our first fiscal quarter, I'm happy to report that we're off to a really solid start for fiscal year 2020. We look forward to providing you

> with a complete update on our February 6 earnings call, but I'd say that ***our quarter is consistent with the guidance we provided in November, and we are on track for the full year.***

228. Investors' utter lack of awareness of the numerous device and regulatory issues impacting Alaris revenues is reflected in a February 3, 2020 research note by Cowen. In the note, the Cowen analysts looked forward to BD's upcoming February 6, 2020 earnings call for first quarter FY20, and predicted that the Company will achieve the "top-end" of guided revenue growth for the period (5% to 5.5%). Notably, the analysts state, "mgmt. publicly revealed that discussions with the FDA were completed and Alaris U.S. shipments returned in full during F1Q."

229. Later in the report, Cowen again noted "[m]anagement's two public disclosures that the Alaris software upgrade was ***completed*** and shipping was ***fully resumed*** in F1Q," remarking that these factors "bode[d] well for the set up relative to expectations and the guidance range."

230. Thus, based on Defendants' consistent representations, the market believed the path had been cleared for the Company to achieve its guided FY20 revenues propelled by the resumed strength of Alaris sales.

4. BD Issues a Voluntary Recall Based on Alaris Software Remediation That Defendants Misleadingly Claim Will Be Fixed Through "Education," "Training," and an Eventual "Software Release"

231. On February 4, 2020, BD issued a recall notification ("February 4 Notification") announcing that it was issuing a "voluntary recall" to address "specific software issues with the BD Alaris™ System Infusion Pumps."

232. The February 4 Notification listed five specific software issues including: (i) software errors related to System Error Code 255-XX-XXX; (ii) delay options programming;

(iii) low battery alarm failure; (iv) keep vein open (KVO)/end of infusion alarms priority; and (v) use errors related to Custom Concentration programming.

233. BD stated that it would undertake two actions to address the identified "issues": "comprehensive education and support on the above issues including reference guides and training videos" and "an upcoming software release."

234. The February 4 Notification did not state or indicate that Alaris devices would be unavailable for sale for any period of time, either under the voluntary recall or otherwise.

235. Indeed, the disclosure cast the recall as addressing technical device issues and related fixes that would have essentially no impact on BD's revenues or financial performance.

236. That same day, BD also sent letters to affected customers about the "voluntary recall." According to BD, the letters aimed to "provide[] important user actions to help mitigate the potential risks until these software issues have been remediated."

237. The letters further disclosed that the FDA had been informed of the voluntary recall and stated that BD had been in discussions with the FDA prior to February 4, 2020 about the "upcoming software version" that was intended to eventually remediate the identified Alaris software issues.

238. Consistent with the February 4 Notification, the letters did not state or indicate that Alaris devices would be unavailable for purchase or sale, for any period of time, nor did they indicate that the FDA had taken any adverse action against BD with respect to Alaris (such as calling for a ship hold and new 510(k)). As a result, the Company's stock price remained artificially inflated on February 4 and 5, 2020.

5. Defendants Finally Reveal the Truth

239. Defendants' fraud was ultimately corrected by their disclosures to the market on February 6, 2020. These corrective disclosures came through information provided in a

Company Form 8-K with an attached earnings press release ("Earnings Release"), and shortly thereafter, on an 8:00 a.m. Eastern Time conference call regarding BD's first quarter FY20 earnings.

240. In the Earnings Release, BD announced:

> ***[BD] is continuing to work with the U.S. Federal Drug Administration (FDA) on its software remediation plan for the Alaris System, which will require additional regulatory filings*** beyond what the company previously anticipated. The company expects to submit its comprehensive regulatory filing in the fourth quarter of fiscal year 2020. In the interim, the company will partner with the FDA and existing customers to ensure continued access to the Alaris System under medical necessity. ***As a result, the company is lowering its full fiscal year revenue and adjusted diluted earnings per share guidance***.

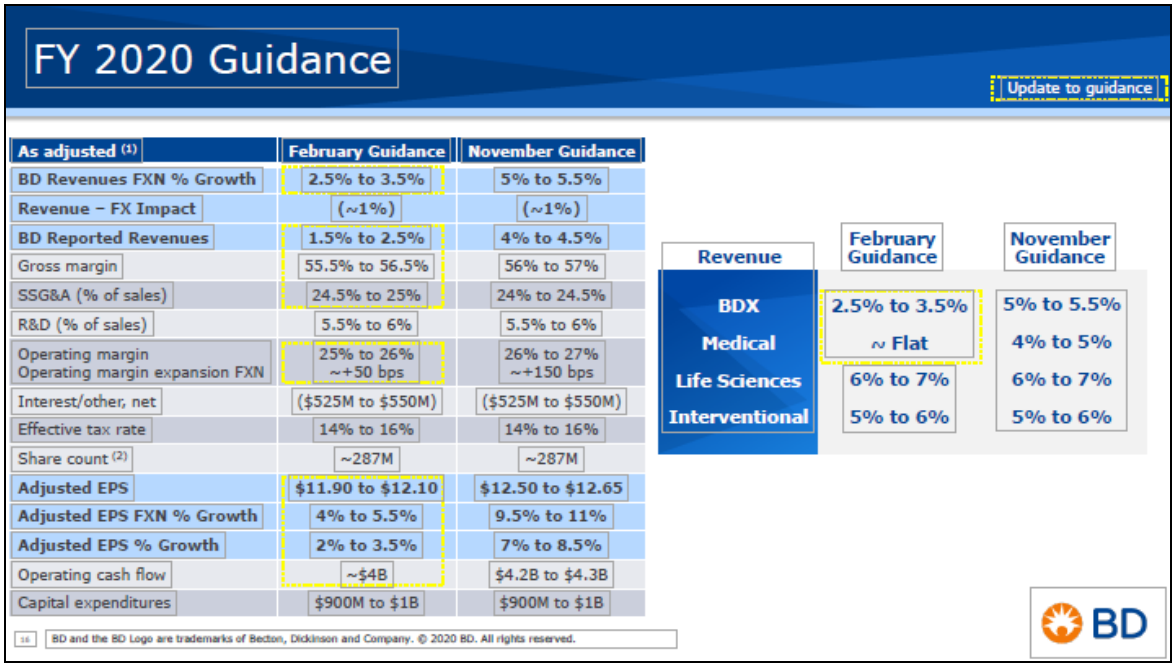
241. The Earnings Release further revealed that BD "is lowering its full fiscal year 2020 revenue and adjusted diluted earnings per share guidance to reflect the impact of the remediation effort and anticipated loss of sales of the Alaris infusion system." The Company stated, as opposed to its prior guidance of 5% to 5.5% growth, that it now expected "full fiscal year 2020 revenues to increase 1.5 to 2.5 percent as reported, or 2.5 to 3.5 percent on a currency-neutral basis."

242. Within approximately an hour, on the earnings call, Defendant Polen further explained to stunned investment analysts that: (i) Alaris would be pulled from the market due to software, device, and related quality issues; and (ii) the FDA was requiring BD to submit a new 510(k) application before resuming Alaris sales. As a consequence, Polen stated, the negative revenue impact to BD in FY20 would be roughly $400 million.

243. These disclosures revealed to the market, for the first time, the significant product and regulatory issues that had plagued Alaris throughout the entirety of the Class Period, but which Defendants had concealed or materially misrepresented. These issues had caused the ship

hold, placed BD's FY20 Alaris revenues in severe jeopardy and rendered Defendants' FY20 Guidance and statements concerning Alaris sales materially false and misleading.

244. Indeed, with respect to financial performance, Defendant Polen detailed how, as a direct result of the Alaris "situation," BD had drastically cut the FY20 Guidance which Defendants had reaffirmed numerous times between November 2019 and January 2020. Specifically, Polen disclosed that "based on this situation, we reduced our guidance range by approximately $400 million in revenue and $0.60 in EPS for fiscal year '20," as reflected on a slide BD presented in conjunction with the earnings call:



FY 2020 Guidance

Update to guidance

As adjusted (1)	February Guidance	November Guidance
BD Revenues FXN % Growth	2.5% to 3.5%	5% to 5.5%
Revenue – FX Impact	(~1%)	(~1%)
BD Reported Revenues	1.5% to 2.5%	4% to 4.5%
Gross margin	55.5% to 56.5%	56% to 57%
SSG&A (% of sales)	24.5% to 25%	24% to 24.5%
R&D (% of sales)	5.5% to 6%	5.5% to 6%
Operating margin Operating margin expansion FXN	25% to 26% ~+50 bps	26% to 27% ~+150 bps
Interest/other, net	($525M to $550M)	($525M to $550M)
Effective tax rate	14% to 16%	14% to 16%
Share count (2)	~287M	~287M
Adjusted EPS	$11.90 to $12.10	$12.50 to $12.65
Adjusted EPS FXN % Growth	4% to 5.5%	9.5% to 11%
Adjusted EPS % Growth	2% to 3.5%	7% to 8.5%
Operating cash flow	~$4B	$4.2B to $4.3B
Capital expenditures	$900M to $1B	$900M to $1B

Revenue	February Guidance	November Guidance
BDX	2.5% to 3.5%	5% to 5.5%
Medical	~ Flat	4% to 5%
Life Sciences	6% to 7%	6% to 7%
Interventional	5% to 6%	5% to 6%

BD

245. The loss of Alaris-related revenues had caused BD to reduce the entire Company's revenue guidance by 2%-2.5%, further reflecting Alaris's importance to BD's bottom line.

246. Defendant Reidy similarly stated that:

> [W]e are revising our revenue growth guidance to 2.5% to 3.5%, specifically due to the Alaris situation. Our updated range reflects several scenarios based on our ongoing conversations with the FDA, with the bottom end of our range assuming

> a very limited ability to ship Alaris pumps this fiscal year. By segment, for the full year, we now expect BD Medical revenue growth to be about flat.

247. After investment analysts sought more detail, Defendant Polen confirmed on the call that "the $400 million, that is essentially is pump capital that we're unable to ship."

248. Reidy echoed: "***So you can think about the takedown as entirely the Alaris pump issue.***"

249. Several analysts pressed Defendants for more information on the news. A William Blair & Company L.L.C. analyst asked about BD's Alaris-related quality systems:

> It seems like some of these software upgrades were kind of already done and you got to kind of repackage them. And then I just want to dig into what specifically did the FDA come in and say that they didn't like about your quality systems? I mean what changes do you think you need to make more broadly on the quality system side?

250. In response, Defendant Polen once again spoke in great detail concerning BD's Alaris-related quality systems and FDA's "ongoing dialogue" with BD regarding the same (although he continued to misrepresent some aspects of BD's discussions with the FDA):

> So as I mentioned, based on the quality system in our Infusion business, we've made software upgrades over time to the Alaris system. And over that period of time, we're talking -- not this year, we're talking a number of years, our quality process determined that those upgrades that we've been making in that business did not require a 510(k) clearance. And so most recently, on the most recent changes and updates that we made, we followed that same process. And our team determined based on that process that those recent updates in November also did not require a new 510(k) clearance. And so we released that software improvement in December, and we resumed shipping, as we had shared with you last month.
>
> Since what we've learned, and as I mentioned, we had a key meeting with the FDA as recently as this Monday, through our ongoing dialogue with the FDA, we learned that the FDA disagreed with that determination about the need for a new 510(k) clearance for the updated software. And that applies not just to the upgraded software that we're talking about in November, but that decision process that had occurred over time. And so as I said, we're collaborating with the FDA on their request to combine all the Alaris software enhancements and remediation upgrades with the additional changes made to the Alaris system over time, right, over years, into a more comprehensive regulatory filing, which is

> going to be submitted this summer. And so while you're right, we are ready to -- we have the information ready for the recent software upgrades, we are -- the work that has to take place between now and the submission date is more in reference to the historical changes that have been made over multiple years going back, and the -- some additional testing that we need to do on those historic changes to reflect the testing requirements today. So that's the work that has to be done.

251. An analyst from Bank of America Merrill Lynch questioned how Defendants purportedly were blindsided by the FDA's actions, stating: "I'm struggling to understand kind of how you got caught offguard and ***how this went from sort of a software upgrade to something much more significant***."

252. Polen responded, again evincing apparent in-depth knowledge of the Alaris-related quality processes and FDA communications that had led to the present circumstance:

> [I]t's not unprecedented where there are situations where over time a product evolves. And then the FDA looks and says, wait a minute, your current 510(k) needs to be updated to reflect those series of changes over time. And in this case, we had a -- there is a process in the business, and there's a specific quality process within the Infusion business within the consent decree that the team was following that said each of those individual changes didn't require a 510(k) process. Again, when the FDA looks back at it over a 5-, 10-year period, they say, wait a minute, you actually need to put in a 510(k) given that series of changes that have been made. And that's the exact work that we're doing.

253. In response to the disclosure of corrective information on the earnings call and in the Earnings Release, BD's stock price cratered, dropping $33.74 (nearly 12%) in one day on unusually heavy trading volume to close at $252.25 on February 6, 2020. The drop eliminated approximately $10 billion in market capitalization and shareholder value.

254. Investment analyst reports and market commentary recognized the direct relationship between the new corrective information and the massive BD stock price decline on February 6, 2020.

255. For example, a report by CFRA issued upon the issuance of the Earnings Release on February 6, 2020 stated: "Shares of BDX declined 10% in pre-market trading on the

unexpected announcement that BDX is working with the FDA on a software remediation plan for the Alaris pump system."

256. Similarly, a report by investment analysts at Wells Fargo that same day noted BD's "unexpected delay in its Alaris pump remediation effort," reporting:

> Management lowered its FY20 revenue growth guidance from 5-5.5% to 2.5-3.5% ex-FX growth, primarily reflecting ~$400MM reduction in pump sales expectation. The EPS guidance is also reduced from $12.50-$12.65 to $11.90-$12.10. Management expects to file the 510K for the Alaris pump in FQ4, although we see a risk of delay into FY21. Bottom-line, we expect the pump issue to remain an overhang given the uncertainty around timing of return to market. That being said, BDX shares are down 11.8% today (vs. S&P 500 +0.3%) with the market cap shrinking by about $10B, suggesting that the market is likely discounting more than just $400MM of potential permanent revenue loss.

257. The Wells Fargo report elaborated:

> Key risk is a delay in Alaris pump's return. Admittedly, there is a lot of uncertainty around timing of Alaris getting back to the market and the risk of a delay is real in our view. While the company is targeting FQ4 filing, we believe BDX may be in relatively early stage of compiling historical software update data from previous years and thus the submission timeline could slip into FY21. Additionally, with a somewhat checkered history (multiple recalls) for Alaris and the pump industry, we believe that FDA review timeline could extend beyond the 6 months. Additional delay in Alaris' return to market could translate to additional lost sales in FY21 and may lead to greater permanent share loss.

6. Post-Class Period Developments

258. Events following the close of the Class Period further reveal the nature and extent of Defendants' fraud, the severity of the regulatory issues involved, and the intensive and time-consuming process BD had to undertake in connection with the Alaris 510(k).

259. On May 7, 2020, Polen, discussing BD's Alaris 510(k) application preparations, told investors during the Company's earnings call for the second quarter of FY20 that his "executive team is directly engaged on this on a daily and weekly basis" and it is "the critical priority for the company."

260. On June 10, 2020, Polen stated during the William Blair 40th Annual Virtual Growth Stock Conference that "[w]e've [BD] got over 150 people now working full time on that [referring to the Alaris 510(k) submission]."

261. It was not until April 26, 2021 that BD announced in a press release that it had finally filed the Alaris 510(k) with the FDA (on April 26, 2021). This was fourteen months after the Company had disclosed on the February 6, 2020 earnings call that it would be filing the 510(k).

262. On August 5, 2021, Defendants conveyed that the FDA had not yet granted 510(k) clearance for Alaris. As of October 28, 2021, BD still had not announced that a 510(k) had been granted.

263. Moreover, on an August 5, 2021 earnings call, Defendant Reidy stated that while it was possible that the FDA's review of the 510(k) application "could be in line with past pump time lines. . . . [I]t was more likely to take longer for the FDA to review and ultimately grant clearance."

264. In addition, BD disclosed in its May 6, 2021 Form 10-Q that the SEC Enforcement Division had commenced an investigation relating to matters concerning Alaris pumps.

265. Specifically, BD disclosed that, in "February 2021," it had received "a subpoena from the Enforcement Division of the SEC requesting information from the Company relating to, among other things, Alaris™ infusion pumps." The SEC Enforcement Division ordinarily determines to issue subpoenas only after conducting preliminary, informal information-gathering and communications with the subject company. BD stated that it was "cooperating with the SEC and responding to these requests," and that it "cannot anticipate the timing, scope, outcome or

possible impact of the investigation, financial or otherwise." BD repeated this disclosure in its Form 10-Q dated August 5, 2021.

V. ADDITIONAL ALLEGATIONS OF SCIENTER

266. The facts discussed above demonstrate that, when making their public statements to investors, Defendants knowingly and/or recklessly misrepresented: the true regulatory and device issues that caused Alaris to stop shipping in 2019-2020, the lack of FDA approval for Defendants' short-lived attempt to end the ship hold, the FDA's position that Alaris would need a 510(k) for required fixes, and the concomitant impacts and severe risks to BD's FY20 revenues.

267. When Defendants Reidy, Polen and Forlenza personally spoke to investors about the ship hold, related discussions with the FDA, and/or BD's FY20 Guidance on numerous occasions during the Class Period, they knew the true facts that they withheld, and that rendered their statements materially false and misleading. For example, FE-6 reports that Polen and Forlenza and the other highest executives at BD were promptly informed of the Pre-Class Period FDA meetings that resulted in the ship hold—the very topic Reidy and Polen discussed in detail on November 5, 2019. Senior management was again promptly informed when the FDA rejected BD's resumption of Alaris shipments in January 2020—the topic Polen spoke publicly and authoritatively about to an investor conference on January 14, 2020. Defendants were informed of these critical events about major Alaris and FDA issues just after they occurred.

268. In addition, Defendants informed themselves about the matters on which they spoke publicly, and thus knew of the basic, material facts they failed to disclose. Defendants Reidy and Polen, for example, made prepared remarks on November 5, 2019, discussing the ship hold in specific detail, characterizing the changes to Alaris that it entailed, the amount of time it would take before Alaris started shipping again, and related discussions with the FDA. Both also

answered investment analyst questions about the ship hold. Forlenza introduced the FY20 Guidance. Defendants Reidy and Polen specifically addressed the status of the ship hold in public statements at investor conferences in December 2019 and January 2020, respectively. Their repeated, detailed discussions of these topics support the inference that they were knowledgeable and informed of the relevant, material underlying facts. Polen's and Reidy's respective statements on February 6, 2020, detailing, respectively, BD's "ongoing discussions" and "ongoing dialogue" with the FDA about the resumed Alaris ship hold and myriad underlying device issues in the time period leading up to February 6, 2020, further reinforce the inference that Reidy and Polen were personally aware of what the FDA had communicated to BD about the Alaris ship hold before and during the Class Period. Before speaking publicly on Alaris and the FY20 Guidance, Defendants reviewed relevant information and informed themselves as to key factors affecting the matters they discussed in their prepared remarks, Q&As and in their presentations as officers of BD. Any such review here, even a cursory one, would have included the fact that the ship hold was called-for by the FDA, as was an Alaris 510(k), and that, in January, the FDA had not approved BD's unilateral resumption of Alaris shipments. If Defendants did *not* inform themselves of the material facts on the topics they addressed, that was sheer recklessness.

269. Defendants, as the senior leaders of the Company, also had access to all available information within BD about the matters on which they spoke publicly. The true facts about the Alaris ship hold and the FDA's explicit positions regarding the need for a 510(k) were widely known, virtually contemporaneously with their occurrence, by BD's executives, managers and personnel, as the reports of numerous FEs show. Defendants had ready access to these facts

from any number of individuals and sources at BD. They either informed themselves, or recklessly failed to inform themselves, of the readily available, relevant facts and information.

270. In addition to the strong inference of Defendants' actual knowledge of the material falsity and misleading nature of their statements to the market, or at a minimum, their reckless disregard for the truth, the following facts further support a strong inference that Defendants knowingly or recklessly made false or misleading statements to investors during the Class Period:

271. ***First***, Defendants Forlenza and Polen were financially motivated to commit securities fraud, as their fraud allowed them to sell BD common stock at artificially inflated prices. In fact, these Defendants realized millions of dollars in inflated stock sales during the Class Period that were suspicious in amount and timing, as detailed below:

Insider	Date	Shares Sold	Weighted Avg. Price[5]	Total Proceeds
Forlenza	12/12/2019	4,717	$265.57	$1,252,693.69
Forlenza	12/12/2019	11,626	$265.57	$3,087,516.82
Forlenza	1/2/2020	33,365	$271.28	$9,051,257.20
Forlenza	1/2/2020	12,083	$271.28	$3,277,876.24
Forlenza	1/8/2020	13,860	$275.19	$3,814,133.40
Forlenza	1/8/2020	4,923	$275.19	$1,354,760.37
Forlenza	1/10/2020	19,675	$275.15	$5,413,576.25
Forlenza	1/10/2020	6,990	$275.15	$1,923,298.50
Forlenza	1/23/2020	6,284	$280.06	$1,759,897.04
Forlenza	1/23/2020	2,180	$280.06	$610,530.80
Forlenza	1/24/2020	7,177	$280.13	$2,010,493.01
Forlenza	1/24/2020	2,489	$280.13	$697,243.57
Forlenza	1/27/2020	25,546	$280.09	$7,155,179.14
Forlenza	1/27/2020	8,860	$280.09	$2,481,597.40
Forlenza	1/28/2020	9,848	$280.96	$2,766,894.08
Forlenza	1/28/2020	28,514	$280.96	$8,011,293.44
Polen	12/16/2019	1,953	$269.63	$526,587.39
Polen	12/16/2019	5,568	$269.63	$1,501,299.84

[5] This number is the weighted average price per share reflected in the Forms 4.

Insider	Date	Shares Sold	Weighted Avg. Price[5]	Total Proceeds
Polen	12/16/2019	1,954	$269.63	$526,857.02
Polen	12/16/2019	4,432	$269.63	$1,195,000.16
	Total	**212,044**		**$58,417,985.36**

272. ***Defendant Forlenza*** sold a total of 198,137 shares of BD common stock throughout the three-month Class Period for total proceeds of **$*54,668,240.95***. These sales were suspicious in amount—in the three-month (93-day) Class Period, Forlenza sold ***four times more*** BD common stock than he sold during the same three-month period the year before (November 5, 2018 to February 5, 2019) and ***twelve times more*** than in the three-month (93-day) period that immediately preceded the Class Period. In fact, Forlenza's sales in the three-month Class Period alone were ***four times*** his sales for the entire calendar year of 2018.

273. The timing of Forlenza's sales was likewise suspicious, as they were clustered: (i) around and after dates on which he is alleged to have made material misrepresentations to investors, which caused or maintained artificial inflation in BD's common stock; and (ii) during the period immediately preceding Defendants' disclosures on February 6, 2020, after which the artificial inflation was removed from BD's share price. Indeed, just nine days prior to Defendants' revelation, ***he sold over 90,000 shares for total proceeds of over $25 million*** in a series of stock dumps between January 23, 2020 and January 28, 2020.

274. Further, nearly all of Forlenza's sales were made pursuant to a 10b5-1 trading plan that he entered into on December 16, 2019—***during the Class Period and while in possession of material, non-public information.*** By this date, for example, the FDA had already stated to BD that Alaris should not be shipping due to extensive defects, and needed a 510(k), and BD had already put Alaris on the ship hold as a result, all of which was communicated up to BD senior executives, including Forlenza. As he knew, Alaris was already being withheld from

the market for these reasons, and the full resumption of Alaris sales in FY20, as was necessary to support BD's FY20 Guidance, was in severe doubt.

275. Forlenza had a unique motivation to keep BD's stock price artificially inflated as high as possible during the Class Period, in the form of his planned stock sales that he disclosed in mid-December 2019. Given Alaris's key role as a revenue generator for BD, if the truth concerning Alaris device and regulatory issues and related revenue impacts had been disclosed to the market any earlier, BD's stock price would predictably and foreseeably have fallen. Indeed, when information reflecting these facts was disclosed on February 6, 2020, BD's stock price fell by nearly 12%, erasing ten billion dollars of market capitalization. By cashing out, and selling over 198,000 shares for over $54 million before the true state of affairs concerning Alaris was revealed, Forlenza avoided losses of approximately $6.4 million on his share sales.

276. Notably, to sell the large amount of common stock Forlenza sold during the Class Period, he exercised stock appreciation rights that were at no risk of expiration—the majority of these rights were not set to expire until November 22, 2021 and small minority (16,343 shares) were to expire on November 23, 2020.

277. ***Defendant Polen*** sold a total of 13,907 shares of BD common stock on or about December 16, 2019 at an average weighted price of $269.63, for total proceeds of $3,749,744.41. Polen's sales were suspicious in amount—his sales exceeded those he made in the three-month (93-day) period directly preceding the Class Period and during the same three-month period the year before (November 5, 2018 to February 5, 2019)—the latter by 18% .

278. Polen's sales followed dates on which he is alleged to have made material misrepresentations to investors, which caused or maintained artificial inflation in BD's common

stock. Moreover, the sales followed a significant, sustained increase in BD's common stock price following Defendants' false or misleading issuance and reaffirmation of FY20 Guidance.

279. Like Forlenza, Polen sold his shares while in possession of material, non-public information. By the date of his sales, the FDA had already stated to BD that Alaris should not be shipping due to extensive defects, and needed a new 510(k), and BD had already put Alaris on the ship hold as a result, all of which was communicated up to BD senior executives, including Polen. Showing his personal knowledge of the relevant facts, Polen had spoken in detail about the interactions with the FDA and the Alaris ship hold on November 5, 2019 (albeit in a materially false and misleading way). As he knew, Alaris had already been withheld from the market for the foregoing reasons, and the full resumption of Alaris sales in FY20, as was necessary to support BD's FY20 Guidance, was in severe doubt.

280. Also like Forlenza, Polen exercised stock appreciation rights that were at no risk of expiration. The majority of the rights Polen exercised to make his large Class Period sales were not set to expire until November 26, 2025 and small minority (3,907 shares) were to expire on November 25, 2024.

281. ***Second***, the alleged fraud concerned BD's core segment, BD Medical, and key product suite, Alaris.

282. As discussed above, the Medical segment made up over half of BD's total annual revenue in FY 2017, 2018, and 2019. BD reported in SEC filings prior to and during the Class Period that BD Medical's underlying revenue growth was "driven" by the "[MMS] unit's installation of dispensing and infusion systems." During FY19, in Forms 10-Q for the second and third quarters, for example, Defendants touted the MMS unit's leading rate of growth, and stated that the BD Medical segment's growth was "attributable to" the growth of MMS.

283. Alaris was in FY19 and throughout the Class Period the MMS unit's largest and most important product line and was routinely identified by the Company as a "[k]ey" product line for BD, including because it served as the linchpin to the Company's "interoperability" strategy. Under this strategy, attendant MMS products including Pyxis dispensing systems and the HealthSight viewer system, which could connect and interface with Alaris, were promoted and sold alongside Alaris. Thus, Alaris drove BD's sales of these products as well. As Forlenza asserted in January 2019, in recent periods "the pumps did exceptionally well. But [the] bigger driver is the connectivity, the interoperability . . . . So as we build that complete system, the pumps are a vital part of that." Across 2019, BD repeatedly pointed to Alaris and the MMS infusion pump business as a main driver BD Medical's, and BD's, strong growth and revenues.

284. Notably, investment analysts covering BD focused on the importance of Alaris as well. For example, a November 4, 2019 analyst report by Zacks noted that Alaris was a product that would continue to "drive the company."

285. Moreover, Defendants repeatedly spoke about and focused investors on Alaris and identified its attendant revenue as a driving force behind BD's FY20 Guidance. Defendants also spoke in detail about the ship hold in public statements, reflecting its importance to investors. For example, Reidy spoke in detail on November 5, 2019 about the ship hold and the resumption of Alaris sales after Q1 of FY20, both in scripted remarks that he would have personally prepared and reviewed, and in Q&A responses to analyst questions about the ship hold and its revenue impacts. Polen also spoke in detail about the purported upgrades to Alaris and discussions with the FDA that related to the ship hold on the same earnings call, reflecting its core importance to BD and its earnings.

286. Defendants' public statements portrayed Alaris as an enormously important device whose sales BD was relying upon to deliver the FY20 growth it had guided to the market. In keeping with the clear importance of Alaris to BD and its ability to grow revenues, the public statements of Defendants—BD's senior-most officers—strongly and plausibly suggest that BD's senior management had detailed knowledge of or access to the material facts and information misrepresented or concealed by Defendants. Indeed, Defendants' public statements demonstrate that each was knowledgeable about and actively involved in, among other things: (i) reviewing, analyzing, and approving BD's FY20 Guidance; (ii) BD's strategy and business with respect to the ship hold on Alaris, which already was not being sold in Q1 of FY20; (iii) monitoring the status of purported software "updates" and "improvements" that they said were being made to Alaris and would be finished in Q1 of FY20; (iv) assessing the impact of Alaris-related revenue on BD's overall performance in FY20; and (v) participating in the Company's interactions with the FDA concerning Alaris and the ship hold. Defendant Polen also had direct involvement and knowledge related to the Company's failed Project Monterey 510(k) application in 2017-2018, which sought 510(k) clearance for the LBA issue, and knew that BD lacked critical Alaris testing and analysis documentation that the FDA had required in that 510(k) application. That Defendants made many of these public statements and offered purported accurate detail in response to direct questions about Alaris from investment analysts only further supports a strong inference of scienter

287. The clear importance of Alaris to BD's financial performance and FY20 Guidance is further confirmed by the fact that, when Alaris sales were eliminated from FY20, it resulted in lowering BD's guided revenue amount by 400 million dollars. It also resulted in BD lowering its guided growth for the entire Company from 5%-5.5% to 2.5%-3.5% on the basis of

the loss of Alaris sales, alone. Defendants explicitly told investors on February 6, 2020 that the drastic cut to FY20 Guidance and expected revenue resulted from the Company's inability to ship and sell Alaris products in FY20.

288. These facts showing Alaris's core importance to BD collectively raise a strong inference that the Individual Defendants either knew, or were reckless in disregarding that their alleged misstatements were materially false or misleading when made.

289. ***Third***, as BD's senior-most executives, the Individual Defendants controlled the contents of the Company's public statements, including in the November 5, 2019 earnings call and at investor conferences thereafter, and in all public statements regarding the FY20 Guidance. In preparing and reviewing Defendants' public statements before their dissemination, the Defendants had access to material, adverse, non-public information about Alaris, including, specifically, knowledge of or access to information about BD's pivotal discussions with the FDA in which the FDA said Alaris should not be shipping due to extensive product issues, that Alaris would need a 510(k) to clear needed fixes, and that BD's unilateral resumption of Alaris sales in December 2019 was not acceptable. Indeed, Defendants Polen and Forlenza were informed of these discussions with the FDA shortly after they concluded, as were numerous other senior executives within BD.

290. These Defendants, because of their high-ranking positions and direct involvement in the everyday business of the Company, directly participated in the management of BD's operations, possessed and exercised the power and authority to control the contents of the Company's SEC filings, press releases, and other market communications, and were privy to confidential information concerning BD and its business, operations and financial statements, and strategy.

291. The Individual Defendants were directly involved in controlling the content of, and in drafting, reviewing, publishing, and/or disseminating, the false or misleading statements alleged herein. Defendants Polen and Reidy in particular spoke in purported extensive detail about the Alaris ship hold and BD's discussions with the FDA regarding the same on November 5, 2019 and during the Class Period. These Defendants reviewed and approved their own public statements before making them, and understood the basis for them (or else were grossly reckless in failing to do so).

292. Defendants were aware or recklessly disregarded that the false or misleading statements and omissions were being issued; and approved or ratified these false or misleading misstatements and omissions, all in violation of the federal securities laws. Because of their positions with the Company, and their access to material non-public information available to them but not to the public, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to and were being concealed from the public, and that the contrary representations being made were then materially false or misleading. The Individual Defendants are thus liable for the false statements and omissions pleaded herein under the Exchange Act. Further, as BD's senior-most officers, the Individual Defendants' knowledge or recklessness is imputed to the Company.

293. ***Fourth***, as BD acknowledged in various Company SEC filings prior to and during the Class Period, BD is subject to extensive federal laws and regulations relating to its development, manufacture and marketing of medical devices and technologies. Violations of those laws and regulations subjected BD to various penalties and business disruptions. Given the fundamental importance of the FDA as a regulator of BD's devices and activities, it may be inferred that the Individual Defendants and those working at their direction closely monitored the

Company's compliance with applicable laws and regulations during the Class Period and were promptly informed of BD's interactions with the FDA with respect to Alaris (as is specifically alleged). Moreover, Defendants Reidy and Polen personally detailed BD's interactions with the FDA specifically related to the Alaris device and regulatory issues in question in their public statements to the market on November 5, 2019, during the Class Period, and again on February 6, 2020, when they each discussed the ongoing communications with the FDA that had occurred in the period of time leading up to that date about the Alaris issues. Reidy's and Polen's repeated public discussions of the Company's interactions with the FDA specifically about the underlying Alaris matters at issue indicate both the significance of the FDA's role with respect to Alaris and BD, and their personal knowledge of what the FDA had communicated to BD about Alaris before and during the Class Period.

294. ***Fifth,*** the temporal proximity and sharp contrast between Defendants' false or misleading statements during the Class Period and BD's disclosures on February 6, 2020, further support a strong inference of scienter. Indeed, just three months after issuing positive FY20 Guidance and proclaiming to investors that Alaris revenue would drive BD's performance in the current year, and ***just nine days after re-affirming that FY20 Guidance yet again***, BD shocked the market by drastically slashing FY20 Guidance because Alaris shipments would be required to stop indefinitely while BD completed a remediation plan and sought 510(k) clearance for Alaris changes, both historical and forthcoming.

VI. DEFENDANTS' MATERIALLY FALSE OR MISLEADING STATEMENTS AND OMISSIONS OF MATERIAL FACT

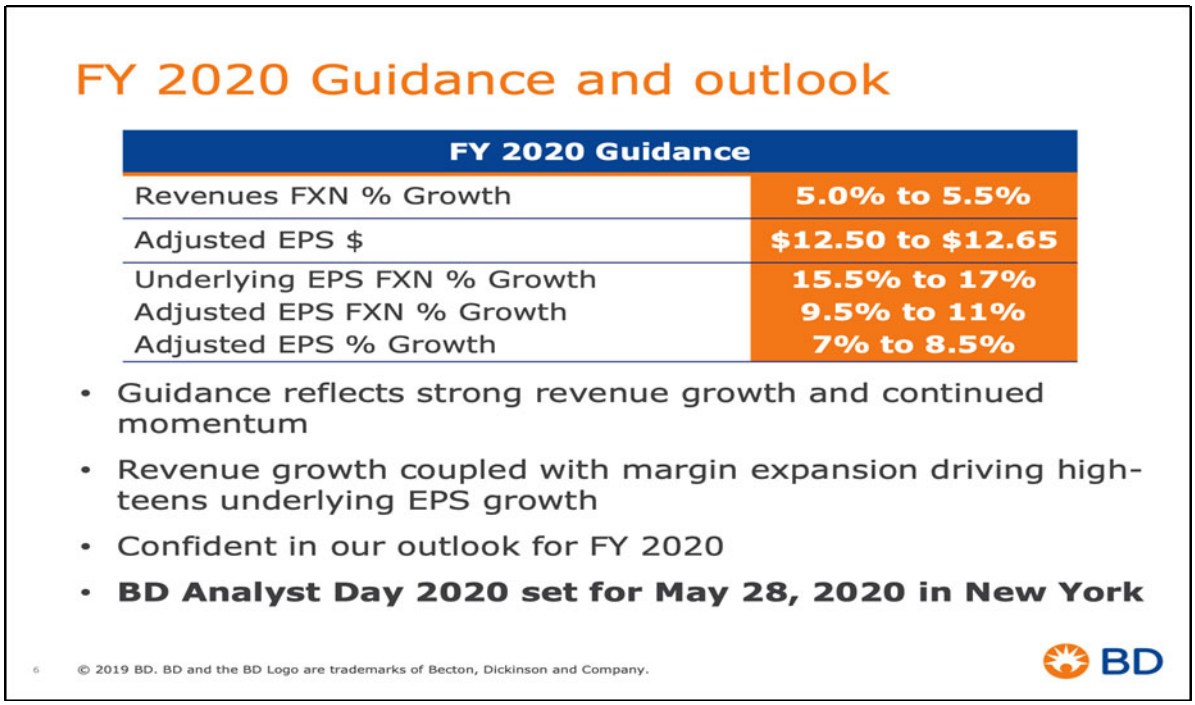
A. November 5, 2019 - Press Release, Earnings Call, and Presentations

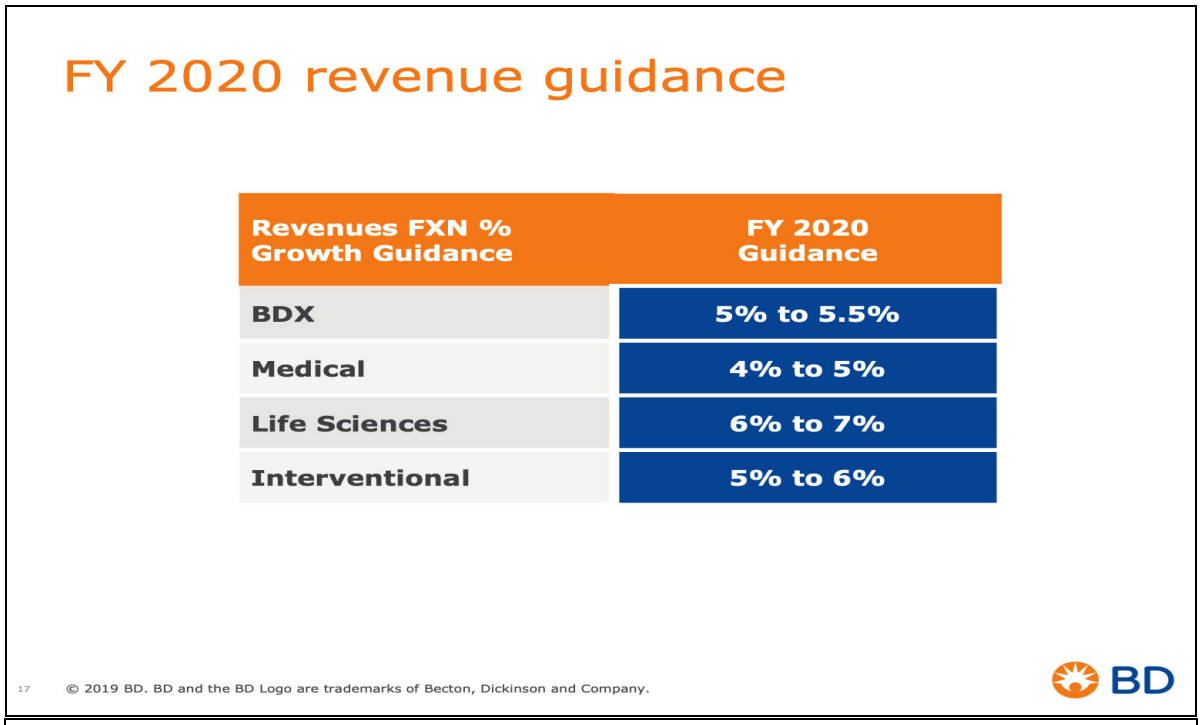
295. On November 5, 2019, BD issued a press release on Form 8-K which, among other things, provided BD's FY20 Guidance.

296. In that press release, BD represented to investors that "***the [C]ompany expects full fiscal year 2020 revenues to increase 4.0 to 4.5 percent as reported, or 5.0 to 5.5 percent on a currency-neutral basis***" and ***"[a]s adjusted, the company expects full fiscal year 2020 diluted earnings per share to be between $12.50 and $12.65, resulting in growth of approximately 9.5 to 11.0 percent on a currency-neutral basis***."

297. The same day, November 5, 2019, BD held an earnings call to discuss the Company's fourth quarter and full year FY19 results and FY20 Guidance. Defendants Forlenza, Reidy, and Polen participated and spoke on behalf of the Company. They made prepared remarks and led investors through an investor presentation entitled "Fourth Quarter and Full Year Results Fiscal Year 2019" and a summary graphic entitled "Q4 & FY19 Financial results," both of which were published to BD's website.

298. The presentation included the following slides reflecting ***BD's FY20 Guidance***, which Defendants discussed and presented during the call with prepared remarks:

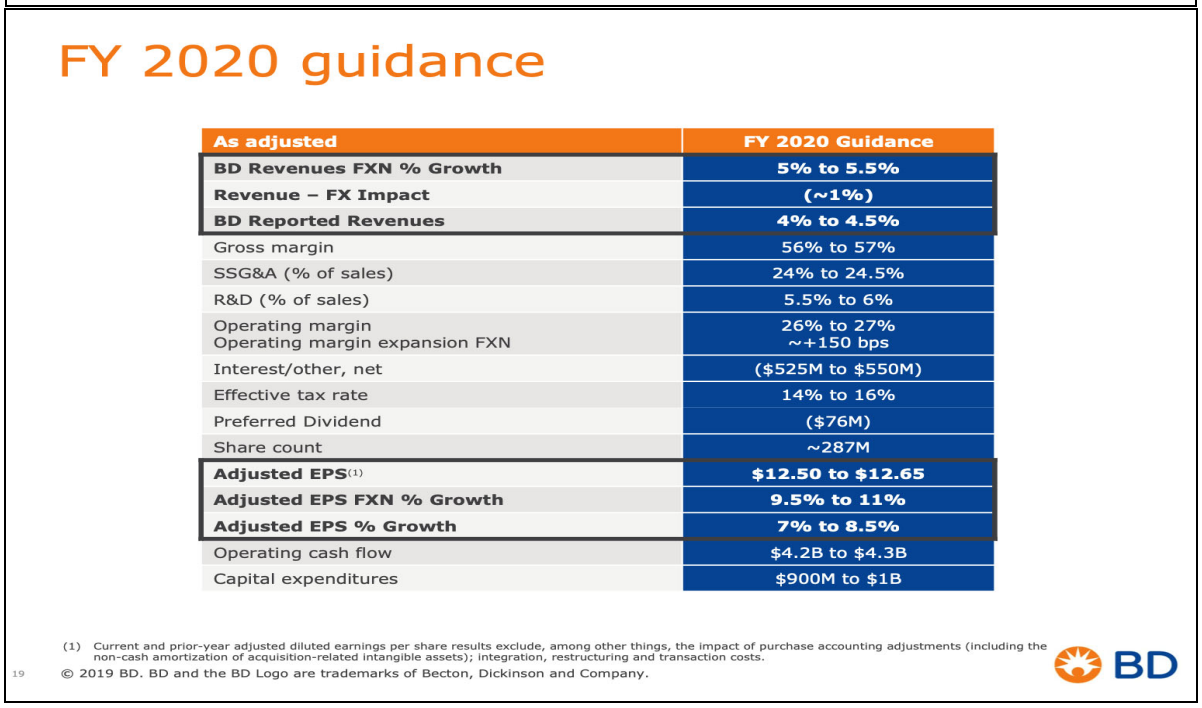




FY 2020 revenue guidance

Revenues FXN % Growth Guidance	FY 2020 Guidance
BDX	5% to 5.5%
Medical	4% to 5%
Life Sciences	6% to 7%
Interventional	5% to 6%

17 © 2019 BD. BD and the BD Logo are trademarks of Becton, Dickinson and Company.



FY 2020 guidance

As adjusted	FY 2020 Guidance
BD Revenues FXN % Growth	**5% to 5.5%**
Revenue – FX Impact	**(~1%)**
BD Reported Revenues	**4% to 4.5%**
Gross margin	56% to 57%
SSG&A (% of sales)	24% to 24.5%
R&D (% of sales)	5.5% to 6%
Operating margin Operating margin expansion FXN	26% to 27% ~+150 bps
Interest/other, net	($525M to $550M)
Effective tax rate	14% to 16%
Preferred Dividend	($76M)
Share count	~287M
Adjusted EPS(1)	**$12.50 to $12.65**
Adjusted EPS FXN % Growth	**9.5% to 11%**
Adjusted EPS % Growth	**7% to 8.5%**
Operating cash flow	$4.2B to $4.3B
Capital expenditures	$900M to $1B

(1) Current and prior-year adjusted diluted earnings per share results exclude, among other things, the impact of purchase accounting adjustments (including the non-cash amortization of acquisition-related intangible assets); integration, restructuring and transaction costs.

19 © 2019 BD. BD and the BD Logo are trademarks of Becton, Dickinson and Company.

299. At the outset of the call, Defendant Forlenza presented BD's FY20 Guidance, directing investors to slide 6 of the presentation and stating:

> ***[Y]ou will see our initial guidance for fiscal year 2020, which reflects continued momentum across our businesses and strong revenue growth of 5% to 5.5%. On the bottom line, we expect to deliver adjusted EPS between $12.50 and $12.65.***

> ***This represents currency-neutral growth of 9.5% to 11% that is driven by strong underlying growth that is breaching high teens. All in all, we expect to drive earnings growth of about 7% to 8.5%. Our outlook is based on our current view of the environment***.

300. Defendant Reidy echoed Forlenza's statements concerning BD's FY20 Guidance, stating: "Moving on to Slide 17 [of the presentation] and our full fiscal year 2020 revenue guidance. ***We expect currency-neutral revenue growth of 5% to 5.5% on a comparable basis***." Reidy further declared that "***[b]y segment, for the full year, we expect BD Medical revenues to grow between 4% and 5%***."

301. Defendant Reidy also claimed BD was planning certain "improvements" and "upgrades" to Alaris and in discussions with the FDA about the "timing of implementations of these upgrades," assuring investors, however, that any such move would simply shift Alaris revenue from first half FY20 to "the balance of the fiscal year":

> ***From a phasing perspective, we expect revenue growth in the first half of the fiscal year to be approximately 100 basis points below the full year guidance range driven by first quarter revenue growth of 1% to 2%. In our MMS business, we are planning to make some improvements to our Alaris pump software, including upgrades to alarm prioritization and optimization. We are in discussions with the FDA about the timing of implementation of these upgrades and the possibility of bundling them with a new software version release. This is expected to move the timing of some sales from Q1 to the balance of the fiscal year***.

302. Evercore ISI analyst, Vijay Muniyappa Kumar, pressed Defendants for more information concerning the purported Alaris pump upgrades and their impact, if any, on the Company's expected FY20 revenue growth, asking:

> I guess the Q1 impact on MMS, I think you mentioned software changes and I think your main competitor is talking about a rollout of a new platform. Can you maybe just talk about the comparative dynamics and whether the software rollout, whether that's just a fourth quarter phenomena? Or usually, when I hear software, I think about integration issues. So just maybe give some color on what's changing there.

303. Defendant Reidy replied: "We did say that we expect revenue growth to be between 1% and 2%, ***and one of the drivers of that is the timing of the upgrades on the Alaris pump software***." Reidy further stated: "Having said that, ***despite the 1% to 2% growth in the first quarter, we expect the first half to be relatively close to guidance of within 100 basis points***. So you kind of have a similar split between first half and second half that you had in '19 driven by a number of those factors."

304. Defendant Polen added considerable apparent detail, explaining that it was part of BD's "process and . . . strategy . . . to continually iterate and make enhancements to the platform" and that the Alaris "upgrade" was "a continued reflection on those investments":

> So just a note. As you know, Alaris is the clear leader and product choice in, not only the infusion market, but also as part of a broader Medication Management Solution that our customers are investing in. ***And it's part of our process and our strategy in the business to continually iterate and make enhancements to the platform. And so you've seen us do that certainly on the hardware side with significant investments, such as the new Alaris M2 pump launch, which has been extremely well received by our customers. And we've been making those same type of investments in software upgrades over the last couple of years. And this upgrade right here is a continued reflection on those investments and will be forthcoming***.
>
> I would just say in terms of momentum, maybe just one other comment there on your question, we saw in FY '19 near or at, I'd say, record levels of continued share gain both in the infusion and the dispensing business, so about 200 basis points of gain in infusion and 100 in dispensing. ***And we see no slowdown in that momentum.***

305. Defendants' bolded statements identified in paragraphs 301 and 303-304 that, *inter alia*, BD had implemented the Alaris ship hold to provide beneficial "upgrades," "improvements," and "enhancements" to Alaris, consistent with and further to BD's customary "process and . . . strategy in the business to continually iterate and make enhancements to the platform" were materially false or misleading when made. These statements misrepresented:

a. the fact that the real reason for the ship hold was that the FDA had told BD in the weeks prior to November 5, 2019, that Alaris should not be shipping given numerous device defects that affected patient safety. Defendants' statements obfuscated the FDA's central role in driving this material event.

b. The statements also misrepresented that the changes to Alaris in question were "upgrades" being undertaken in the normal course of BD's process to "continually iterate and make enhancements," when, in reality, the changes addressed a number of significant patient safety issues with Alaris whose remediation was happening at that time, disrupting BD's business, specifically because it had been called-for by the FDA.

c. The statements also misrepresented the extent and severity of the Alaris issues underlying the ship hold, portraying them as addressable through normal upgrades that could be completed within several weeks, when in fact: (i) certain of the safety issues (e.g., the LBA issue) had not been resolved through prior efforts by BD and had persisted for years; and (ii) the FDA had told BD that Alaris would require new 510(k) regulatory clearance in connection with required fixes, reflecting the significance and scope of the modifications involved.

d. The statements also misrepresented the fact that, with respect to at least one of the Alaris issues underlying the ship hold, the LBA issue, BD had itself acknowledged to the FDA that a 510(k) would be needed in order to clear the correction for the problem.

e. The statements further misrepresented the scope of work and amount of time the changes to Alaris that the FDA had called for would require, given that the FDA had stated that a 510(k) was needed for the changes, and that BD was not prepared to complete and submit a 510(k) application—which, once submitted, would take potentially several months for the FDA to review and determine. Thus, the Alaris ship hold would likely be required to continue for an indefinite period of time, all the while impacting Alaris revenues.

306. Defendants' bolded statements identified in paragraphs 301 and 304 downplaying and mischaracterizing BD's ongoing discussions with the FDA as limited to perfunctory questions of implementation and timing, and representing that the pause in Alaris shipments was a fleeting, several-week delay with no impact on overall FY20 Alaris sales and revenue were materially false or misleading when made for the reasons set forth in paragraph 305.

307. Defendants' bolded statement identified in paragraph 304 that BD could "***see no slowdown in that momentum***" of Alaris share gains as of November 2019, one month into Q1 FY20, were materially false or misleading when made for the reasons set forth in paragraph 305. For example, the FDA's undisclosed role in calling for the ship hold which was already impacting Alaris sales, and its undisclosed statement that a 510(k) would be required for needed Alaris changes, presented manifest barriers and brakes on the momentum of Alaris's prior share gains. The ship hold was already impacting Alaris sales, and the need for a 510(k) meant that the prospect of Alaris sales resuming within FY20 was extremely remote.

308. In addition, Defendants' statements issuing and detailing the FY20 Guidance as set forth in paragraphs 296-301 and 303 (including on the slides that BD presented), were materially false and misleading because they lacked a reasonable basis in fact. In particular, they

did not reflect or take into account the undisclosed adverse facts summarized in paragraph 305 which bore directly on whether and the extent to which BD would derive revenues from Alaris sales in FY20. BD's ability to achieve the FY20 Guidance was predicated on its ability to resume selling Alaris in or around Q1 FY20. But given the FDA's explicit statements that Alaris should not be shipped given identified device issues and would need a new 510(k), and the amount of time it would foreseeably take to develop remediations and then prepare, submit and obtain a 510(k), there was no reasonable basis to think that Alaris could be shipped and sold near the end of Q1 FY20 and thereafter. Accordingly, Defendants had no reasonable basis to project that their growth would normalize and be propelled in and after Q2 FY20 on account of Alaris sales returning in full. Defendants thereby misrepresented BD's true financial condition and growth prospects, which Defendants represented were anchored by Alaris revenue and Alaris's "interoperability" with other BD products. Such financial guidance was also misleading because, at the time it was issued, Defendants did not disclose specific, material information concerning the regulatory and device issues plaguing Alaris and underlying the ship hold (as set forth in paragraph 305) which, had it been disclosed, would have reasonably called into doubt BD's financial guidance. Having elected to issue financial guidance, Defendants violated their duties to: (i) disclose such specific information so as to render BD's financial guidance not misleading; and (ii) update BD's financial guidance when Defendants became aware of such information.

B. November 21, 2019 - Jefferies London Healthcare Conference

309. On November 21, 2019, John E. Gallagher, BD's SVP, Treasurer, and CFO of BD Medical, attended, presented, and spoke on behalf of BD at the Jefferies London Healthcare Conference.

310. At the conference, Brandon Couillard, a Jefferies LLC analyst, asked Gallagher to explain "some of the phasing of expectations on a top line perspective."

311. Gallagher responded, "[a]s far as Q1 phasing, we did call out Q1 being a 1% to 2% grower. There are a number of dynamics there that are driving it, which effectively create a bit of an imbalance first half, second half. Meaning with a 1% to 2%, we're expecting the first half to be about 4%, ***the back half to be about 6%***."

312. Couillard then asked Gallagher what factor or factors drove the Company's FY20 Guidance:

> If you look at the sort of the guidance that you established for '20 just recently on the fourth quarter call a few weeks ago, kind of talked about 5% to 5.5% organic growth on top line. ***Can you walk us through some of the factors that you've kind of contemplated some of the puts and takes? You also mentioned kind of 1% to 2% organic growth, I think, in the first quarter of the year. So just kind of help us with some of the phasing of expectations on a top line perspective, and then I would like to touch on bottom line as well.***

313. Gallagher sought to allay any concerns over a delay in installments or shipments of Alaris products during FY20:

> ***[P]robably one of the larger ones to call out as well is Alaris pumps. We're upgrading some software. This is in our MMS business, our infusion pumps. We're upgrading some software in the pumps, and that will delay some installations and shipment into the subsequent quarters, and we anticipate getting all of that back inside of the fiscal year***.

314. Couillard further asked, "what parts of the portfolio do you expect to grow faster, slower because -- as you look into '20? What areas do you have the most runway, let's say, for future share gains?"

315. Gallagher responded:

> ***Of course, the other one is in our MMS business, where we've seen very, very strong growth in our Alaris pump business. That -- and although we do see some timing outside of Q1 and into the subsequent quarters of fiscal '20,*** we posted our strongest ever revenue dollars in the MMS business in the fourth quarter, and ***we expect that momentum to continue when you look at the full year of fiscal '20***. So those are a couple of highlights that I'd mention within Medical.

316. Defendant BD's bolded statements identified in paragraphs 311, 313, 315 were materially false or misleading when made for the reasons set forth in paragraphs 305-308. For example, BD's statements regarding the FY20 Guidance and the phasing of BD's projected growth lacked a reasonable basis because they were explicitly predicated on Alaris's return to market in or around the end of Q1 FY20. However, severe regulatory impediments—including the FDA's statement to BD that a 510(k) would be needed for Alaris, and the lengthy and challenging task of developing device fixes, preparing a 510(k) submission and seeking and obtaining clearance from the FDA—meant that BD lacked a sound basis to assert that Alaris's return to market in that timeframe was realistic or plausible.

317. For the same reasons, BD's statements regarding the anticipated strength of Alaris sales and shipments that would contribute to BD's FY20 revenues—for example, that BD would get "all of" its installations and shipments (and hence revenues) for Alaris "back inside the fiscal year," and touting Alaris "growth" and "momentum" within "fiscal '20"—were materially false or misleading.

318. In addition, BD's statement characterizing the Alaris ship hold, stating that it was "upgrading some software in the pumps," was materially false and misleading for the reasons that are set forth in paragraph 305, above. BD was in fact attempting to remediate numerous device safety issues at the behest of the FDA, through modifications that would require it to seek a new 510(k) for Alaris.

C. November 27, 2019 - FY19 Form 10-K

319. On November 27, 2019, the Company filed its FY19 Form 10-K for the period ending September 30, 2019, which was approved, signed and certified by Defendants Forlenza and Reidy.

320. Defendants BD, Forlenza, and Reidy represented in the FY19 Form 10-K the following about the FDA's regulations and expectations:

> ***Our failure to comply with the applicable good manufacturing practices, adverse event reporting, and other requirements of these agencies could delay or prevent the production, marketing or sale of our products and result in fines, delays or suspensions of regulatory clearances, warning letters or consent decrees, closure of manufacturing sites, import bans, seizures or recalls of products and damage to our reputation***. More stringent oversight by the FDA and other agencies in recent years has resulted in increased enforcement activity, which increases our compliance risk.

321. This statement was materially false or misleading because it described as contingent ("could delay or prevent the … marketing or sale of our products") an event and circumstance that had already come to pass. Indeed, the FDA had called for the ship hold on the basis of learning of numerous significant Alaris device and safety issues, and was the impetus for the ship hold that was already keeping Alaris from the market, and already impacting BD's revenues from Alaris in FY20, with no end in sight. Plaintiff also incorporates the allegations set forth in paragraph 305.

322. Defendants BD, Forlenza, and Reidy also represented in the FY19 Form 10-K the following about the Amended Consent Decree and BD's obligations thereunder:

> We also cannot currently predict whether additional monetary investment will be incurred to resolve this matter or the matter's ultimate impact on our business. ***We may be obligated to pay more costs in the future because, among other things, the FDA may determine that we are not fully compliant with the amended consent decree and therefore impose penalties under the amended consent decree***, and/or we may be subject to future proceedings and litigation relating to the matters addressed in the amended consent decree. ***As of September 30, 2019, we do not believe that a loss is probable in connection with the amended consent decree,*** and accordingly, we have no accruals associated with compliance with the amended consent decree.

323. This statement was materially false or misleading for the reason set forth in paragraph 321.

324. Defendants BD, Forlenza, and Reidy further stated in the FY19 Form 10-K:

> As a result of the CareFusion acquisition, we are operating under a consent decree with the FDA relating to our U.S. infusion pump business. ***The consent decree authorizes the FDA, in the event of any violations in the future, to order us to cease manufacturing and distributing products, recall products or take other actions, and we may be required to pay significant monetary damages if we fail to comply with any provision of the consent decree.***

325. This statement is materially false or misleading for the reasons set forth in paragraph 321. Namely, by November 27, 2019, the FDA under its authority over BD, had already called for the ship hold, i.e., the cessation of Alaris shipments. The FDA had also called for a new 510(k) premarket clearance for Alaris.

326. Relatedly, Defendants BD, Forlenza, and Reidy represented in the FY19 Form 10-K that "[d]elays in obtaining necessary approvals or clearances from the FDA or other regulatory agencies or changes in the regulatory process may also delay product launches and increase development costs" and that:

> The design, manufacture and marketing of medical devices involve certain inherent risks. Manufacturing or design defects, component failures, unapproved or improper use of our products, or inadequate disclosure of risks or other information relating to the use of our products can lead to injury or other serious adverse events. ***These events*** could lead to recalls or safety alerts relating to our products (either voluntary or as required by the FDA or similar governmental authorities in other countries), and ***could result, in certain cases, in the removal of a product from the market***. A recall could result in significant costs and lost sales and customers, enforcement actions and/or investigations by state and federal governments or other enforcement bodies, as well as negative publicity and damage to our reputation that could reduce future demand for our products. Personal injuries relating to the use of our products can also result in significant product liability claims being brought against us. ***In some circumstances, such adverse events could also cause delays in regulatory approval of new products or the imposition of post-market approval requirements***.

327. This statement is materially false or misleading for the reasons set forth in paragraph 321. Namely, it was a material misrepresentation to state that action by the FDA "could" cause a device to be removed from the market or "the imposition of post-market approval requirements" when the FDA had already done those very things with respect to Alaris.

As Defendants knew, the FDA had expressly called for and driven the Alaris ship hold that was now in place, and had told BD that Alaris would need a new 510(k) premarket clearance.

328. Thus, Defendants BD's, Forlenza's and Reidy's bolded statements identified in paragraphs 320, 322, 324, 326 were materially false or misleading when made for the reasons set forth in paragraph 305 and 321 and because they characterized as contingent or speculative risks that had already come into being and that were reasonably expected to occur. At the time of these Defendants' statements, the FDA had already taken action that was already impacting Alaris sales, by stating that the product should not be shipping and thus driving the ship hold. Furthermore, the ship hold had no clear end in sight, because the FDA had also said that a 510(k) was required for needed Alaris changes—and the 510(k) preparation, submission and review process is necessarily lengthy and uncertain. Thus, far from a mere risk that the FDA would take the noted steps, Alaris shipments had already been put on-hold, and sales were already being delayed indefinitely, and a 510(k) was already called-for, due to FDA action.

D. December 4, 2019 - Evercore HealthCONx Conference

329. On December 4, 2019, Defendant Reidy attended and spoke on behalf of the Company at the Evercore HealthCONx Conference.

330. During the conference, Evercore ISI analyst, Vijay Muniyappa Kumar, asked Reidy to discuss competition in the pump side (i.e., Alaris) business:

> And switching on to medical, on the med delivery side. I feel like your main competitor on the pump side, they've been, I guess, a little bit more optimistic on what they can do to the market with their new pump launches. Has anything changed at all in the competitive side for you guys on the pump side, Chris?

331. Defendant Reidy replied:

> ***No***. Actually, the pump side, we've been taking 200 points of share last year, and ***we see that continuing, and we have some visibility to that.*** So we don't see that being the case.

> And I think when you look on the dispensing side, 100 points a share. One of the things that's driving that, that sometimes gets overlooked is our HealthSight middleware that sits over this. ***So we have a lot of connectivity across our product lines there that no other competitor has, and great advantages to that***.

332. Defendants' statements indicating that nothing had changed to impact Alaris's competitive position, and that BD could see that Alaris's market share growth was continuing, were materially false and misleading for the reasons set forth in paragraph 305. For example, BD knew that the FDA had called for the ship hold that was now impacting Alaris sales, and that the hold would, due to the need for extensive remediation and new FDA premarket clearance, go on indefinitely.

333. Kumar then asked specifically about the timing of Alaris revenue delays: "Just maybe a big picture on medical. I know you had revenue deferral related to the software chain on the pump side, but that's more of a . . . ."

334. Defendant Reidy responded: "***That's a timing issue. First half issue, yes***."

335. This statement was materially false or misleading because it misrepresented the true facts underlying the ship hold, including the FDA's statements calling for the hold and asserting that a 510(k) would be required for Alaris. Defendants had no reasonable basis to assert or suggest that the Alaris ship hold "issue" would be resolved in the first half of FY20 given that the process of remediation and regulatory clearance that the FDA had indicated was necessary would foreseeably require a much longer period of time.

336. Defendant Reidy's and BD's bolded statements identified in paragraphs 331 and 334 were also materially false or misleading when made for the reasons set forth in paragraphs 305-308.

E. January 14, 2020 - JPMorgan Healthcare Conference

337. On January 14, 2020, Defendants Reidy and Polen attended and spoke on behalf of the Company at the JPMorgan Healthcare Conference and also provided and presented an investor slide deck entitled "Introducing the Next Phase of Value Creation for BD," which was published on BD's website.

338. At the outset, Polen re-affirmed BD's FY20 Guidance and once more re-assured investors that BD was "very much on track for the full year" FY20 Guidance:

> So before I move on and discuss our capital allocation strategy, let me just pause and make a quick comment on the results for our first quarter. We're off to a really solid start for FY 2020. We just closed our books. And of course, we will provide a complete update in February, but ***I'd say our first quarter is consistent with the guidance we've provided in November, and we remain very much on track for the full year***.

339. Defendants BD, Reidy, and Polen also presented and re-affirmed ***BD's FY20 Guidance*** in the accompanying investor slide deck, as reflected in the below slide:

340. Defendants' bolded statements identified in paragraphs 338-339 (including the whole slide) were materially false or misleading when made for the reasons set forth in paragraphs 305-308. In particular, Defendants' statements lacked a reasonable basis, because

BD's ability to meet its FY20 Guidance was predicated on Alaris returning to market and driving BD's growth after Q1 of FY20. However, the FDA's statements that the device should not be shipped after learning of serious product and safety issues, and its statement that Alaris would need a new 510(k) (which would require a lengthy and involved process of remediating the device then seeking FDA clearance), meant that Alaris's return to market for the remainder of FY20 was in acute peril. To the extent BD had already resumed shipping Alaris at this time, Defendants knew (but did not publicly disclose) that the FDA had not been informed of that step, and had not approved or accepted it.

341. Robert Justin Marcus, an analyst from JP Morgan Chase & Co, then asked Defendant Polen for an update on Alaris shipments and Defendants' ongoing discussions with the FDA concerning Alaris:

> Another issue from fourth quarter built into guidance for 2020 was in the pump shipments that you are holding off on some of the shipments as you await a guidance from the FDA around fixing some of the alarms. Any update on how that progressed?

342. Defendant Polen declared that BD had: "***Fully resumed shipping in the first quarter***. ***So we're back to shipping in Q1 to the majority of our customers***."

343. When Marcus pressed further, asking "[a]nd so that played out as expected?" Polen responded: "***Exactly as expected***."

344. Defendant's bolded statements identified in paragraphs 342-343 claiming BD's temporary pause on Alaris shipments had ended and the matter of the Alaris software "updates" and "improvements" had played out "exactly as expected" were materially false when made for the reasons set forth in paragraphs 305-308 and 340. Perhaps above all, these misrepresentations were false and misleading because they omitted the fact that the FDA had not known about BD's

unilateral release of the ship hold, had not approved it, and rejected BD's lifting of the hold when it learned of it. BD reinstated the ship hold immediately thereafter.

F. January 28, 2020 - Annual Shareholders Meeting

345. On January 28, 2020, the Company held its Annual Shareholders Meeting and provided investors with a presentation entitled "Annual Meeting of Shareholders," which was published on BD's website.

346. During the shareholders' meeting, Defendant Forlenza again represented BD was "on track" to meet FY20 Guidance:

> I'm happy to report that we're off to a really solid start for fiscal year 2020. We look forward to providing you with a complete update on our February 6 earnings call, but ***I'd say that our quarter is consistent with the guidance we provided in November, and we are on track for the full year***.

347. Defendant Forlenza also re-affirmed the Company's ***FY20 Guidance*** in the accompanying presentation.

348. Defendant Forlenza sold $10 million worth of BD shares on this date.

349. Defendant's bolded statements identified in paragraphs 346-347 reaffirming FY20 Guidance and claiming BD was "on track for the full year" were materially false or misleading when made for the reasons set forth in paragraphs 305-308, 340 and 344. Defendants had no reasonable basis to assert that BD's FY20 Guidance was on track or projected to be achieved, when it was reliant on sales of Alaris. As Defendants knew, the FDA had called for an Alaris ship hold based on device and safety defects, and for a new 510(k) for the device. When Defendants had unilaterally lifted the ship hold after making certain partial fixes, the FDA had rejected the move, and reaffirmed its explicit position that the device should not be shipped and required a new 510(k). The needed remediation and regulatory submission and clearance process would take an indefinite period of time to complete. As such, there was no basis to

believe or assert BD would achieve its FY20 Guidance, predicated in large part on Alaris sales in FY20 that were no going to happen, and Defendants' statements were materially false.

G. February 4, 2020 - BD's "Voluntary" Recall Notification

350. On February 4, 2020, less than two days before the Company's premarket first quarter FY20 earnings call on February 6, 2020, Defendants announced in the February 4 Notification a "voluntary recall" to address specific software issues with Alaris.

351. In that February 4 Notification, Defendants stated that "BD is issuing a ***voluntary recall*** to address specific software issues with the BD Alaris™ System Infusion Pumps" and that "***BD intends to address the issues through an upcoming software release. BD will update the software for affected devices at no charge and will contact affected customers to initiate the scheduling process for the software update when the software becomes available***."

352. Defendants' bolded statements identified in paragraph 351 were materially misleading when made for the reasons set forth in paragraphs 305 and 349 and because they cast the recall as addressing matters that would have essentially no impact on BD's ability to sell Alaris, and, thus, BD's financial performance. However, BD knew that its unilateral step of lifting the Alaris ship hold had been rejected by the FDA, and that the FDA had confirmed its previously-stated position that the device should not be shipped, and needed a new 510(k)—and that, as a result, Alaris was once again on a ship hold. Moreover, BD has admitted in briefing to this Court that, at *least* by this date, it knew definitively that the FDA would be requiring a 510(k) for Alaris that would cause Alaris generally to not be sold indefinitely.

VII. LOSS CAUSATION

353. Defendants' wrongful conduct, as alleged herein, directly and proximately caused the economic loss suffered by Plaintiff and the Class. During the Class Period, Plaintiff and the Class purchased BD common stock at artificially inflated prices and were damaged thereby when

the price of BD common stock declined when the truth was revealed. (Plaintiff incorporates here the allegations at paragraphs 239-257, set forth above, in full).

354. Throughout the Class Period, the price of BD common stock was artificially inflated and/or maintained as a result of Defendants' materially false or misleading statements and omissions. The price of BD common stock significantly declined (causing investors to suffer losses) when Defendants' materially false or misleading statements, alleged herein to have been concealed from the market, and/or the effects thereof and information relating thereto, were revealed and/or the risks that had been fraudulently concealed by the Defendants materialized.

355. As a result of the disclosure of the truth of Defendants' fraud, BD's stock price dropped $33.74 (nearly 12%) in one day on unusually heavy trading volume, to close at $252.25 on February 6, 2020.

356. It was entirely foreseeable that Defendants' materially false or misleading statements and omissions discussed herein would artificially inflate and/or maintain the price of BD common stock. It was also foreseeable to Defendants that the revelation of the truth would cause the price of the Company's common stock to fall when the artificial inflation caused or maintained by Defendants' misstatements and omissions was removed. Thus, the stock price decline described above was directly and proximately caused by Defendants' materially false or misleading statements and omissions.

VIII. DEFENDANTS FORLENZA AND POLEN ENGAGED IN INSIDER TRADING IN VIOLATION OF SECTION 20A

357. As discussed above, throughout the Class Period, Defendants Forlenza and Polen each were in possession of material, non-public information ("MNPI") regarding the Company, including about the nature, extent, and revenue impact of extensive, undisclosed regulatory and product issues regarding Alaris.

358. Defendants Forlenza and Polen learned these facts and were in possession of such MNPI through, among other ways, their control of BD as the Company's senior executives and participation in or knowledge derived from meetings with the FDA concerning Alaris. Further, Defendants were intensely focused on Alaris, indicating it was a primary driver for FY20 Guidance, and repeatedly spoke to investors about topics specific to Alaris and the FDA. *See, e.g.*, Sections IV.B.4; IV.D. Indeed, these Defendants are alleged to have made false or misleading statements (*see* Sections IV.D and VI) and Forlenza signed BD's 2019 Form 10-K in which facts were misstated and omitted. *See* Sections V., VI.C.

359. While in possession of the foregoing MNPI concerning BD, and contemporaneously with purchases of BD common stock by Class members, Defendants Forlenza and Polen unloaded 198,137 and 13,907 of their personally-held shares of BD common stock, respectively in open market sales, exclusive of sales to the issuer. Forlenza reaped $54,668,240.95 in proceeds from these sales, while Polen took home $3,749,744.41 in proceeds.

360. Contemporaneously with Forlenza's and Polen's sales, Plaintiff purchased 23,754 shares of BD common stock at inflated prices, as reflected in the chart below:

Defendants' Insider Sales					**Plaintiff Purchases**		
Date	**Insider**	**Shares Sold**	**Weighted Avg. Price**	**Proceeds**	**Date**	**Shares Bought**	**Price Per Share**
12/12/2019	Forlenza	11,626	$265.57	$3,087,516.82	12/12/2019	200 200 400	$264.55 $263.38 $264.63
					12/13/2019	900	$268.19
12/16/2019	Polen	1,954 4,432	$269.63 $269.63	$526,857.02 $1,195,000.16	12/16/2019	1,200 200	$269.14 $268.66
					12/17/2019	865	$269.59
					12/18/2019	600	$267.32
					12/19/2019	600	$267.64
					12/20/2019	520	$271.66
1/2/2020	Forlenza	33,365	$271.28	$9,051,257.20	1/6/2020	2,300	$273.47

Defendants' Insider Sales					Plaintiff Purchases		
						695	$272.55
					1/7/2020	3,000	$273.10
1/8/2020	Forlenza	13,860	$275.19	$3,814,133.40	1/8/2020	172 2,600 200	$274.79 $273.61 $272.61
1/10/2020	Forlenza	19,675	$275.15	$5,413,576.25	1/13/2020	900	$275.12
					1/14/2020	1,800 272	$274.96 $276.02
1/23/2020	Forlenza	6,284	$280.06	$1,759,897.04	1/23/2020	188 600	$278.99 $278.75
1/24/2020	Forlenza	7,177	$280.13	$2,010,493.01	1/24/2020	200 300 400	$279.54 $278.49 $279.43
1/27/2020	Forlenza	25,546	$280.09	$7,155,179.14	1/27/2020	200 100 600	$276.41 $277.55 $279.90
1/28/2020	Forlenza	28,514	$280.96	$8,011,293.44	1/28/2020	200 1,000	$282.40 $281.66
					1/29/2020	800	$282.40
					1/30/2020	1,300 242	$280.76 $280.73

361. Upon information and belief, thousands of other Class members also purchased shares contemporaneously with the Defendants' sales identified in the table just above. As alleged in this Complaint, at the time of these Defendants' sales and the purchases by Plaintiff and other Class members, the price of BD's common stock was artificially inflated and/or maintained by the Defendants' material misstatements and omissions.

IX. CLASS ACTION ALLEGATIONS

362. Plaintiff brings this action on its own behalf and as a class action pursuant to Rules 23(a) and (b)(3) of the Federal Rules of Civil Procedure on behalf of a class consisting of all persons and entities who purchased the common stock of BD from November 5, 2019 through and including February 5, 2020, and were damaged thereby. Excluded from the Class are: (i) Defendants; (ii) present or former executive officers of BD or any of BD's subsidiaries or

affiliates, members of BD's Board of Directors, and members of the immediate families of each of the foregoing (as defined in 17 C.F.R. § 229.404, Instructions (1)(a)(iii) and (1)(b)(ii))); (iii) any of the foregoing individuals' and entities' legal representatives, heirs, successors, or assigns; and (iv) any entity in which any Defendant has a controlling interest.

363. The members of the Class are so numerous that joinder of all members is impracticable. During the Class Period, BD had more than 270 million shares of common stock outstanding and actively trading on the NYSE. While the exact number of Class members is unknown to Plaintiff at this time and can only be ascertained through appropriate discovery and procedure, Plaintiff believes that the proposed Class numbers in the thousands and is geographically widely dispersed. Record owners and other members of the Class may be identified from records maintained by the Company or its transfer agent and may be notified of the pendency of this action by mail, using a form of notice similar to that customarily used in securities class actions.

364. Plaintiff's claims are typical of the claims of the members of the Class. All members of the Class were similarly affected by Defendants' alleged conduct in violation of the Exchange Act as complained of herein. Plaintiff has no interests that are adverse or antagonistic to the interests of other Class members.

365. Plaintiff will fairly and adequately protect the interests of the members of the Class. Plaintiff has retained counsel competent and experienced in class and securities litigation.

366. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. The questions of law and fact common to the Class include:

(i) whether Defendants violated the federal securities laws by their acts and omissions as alleged herein;

(ii) whether Defendants' statements to the investing public during the Class Period misrepresented and/or omitted material facts;

(iii) whether and to what extent the market price of BD's common stock was artificially inflated and/or distorted during the Class Period due to the misrepresentations and/or omissions alleged herein;

(iv) whether Defendants named under Section 10(b) of the Exchange Act acted with the requisite level of scienter;

(v) whether reliance may be presumed pursuant to the fraud-on-the-market doctrine and/or the *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128 (1972) presumption;

(vi) whether the members of the Class have sustained damages as a result of the conduct complained of herein and, if so, the proper measure of damages; and

(vii) whether the Individual Defendants were controlling persons of the Company.

367. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy because, among other things, joinder of all members of the Class is impracticable. Furthermore, because the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

X. THE FRAUD ON THE MARKET PRESUMPTION OF RELIANCE APPLIES

368. At all relevant times, the market for BD's common stock was efficient for the following reasons, among others:

(i) BD's common stock met the requirements for listing, and was listed and actively traded on the NYSE, a highly efficient and automated market;

(ii) As a regulated issuer, BD filed periodic public reports with the SEC and the NYSE, in addition to the Company's frequent voluntary public dissemination of information;

(iii) BD regularly and publicly communicated with investors via established market communication mechanisms, including through regular disseminations of press releases on the national circuits of major newswire

services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and

(iv) BD was followed by multiple securities analysts employed by major brokerage firms who wrote reports, which were distributed to the sales force and certain customers of their respective brokerage firms. Each of these reports was publicly available and entered the public marketplace.

369. As a result of the foregoing, the market for BD's common stock promptly digested current information regarding BD from all publicly available sources and reflected such information in the price of BD's stock. Under these circumstances, all purchasers of BD's common stock during the Class Period suffered similar injury through their purchase of BD's stock at artificially inflated prices and a presumption of reliance applies.

370. Further, at all relevant times, Plaintiff and other members of the putative Class reasonably relied upon Defendants to disclose material information as required by law and in the Company's SEC filings. Plaintiff and the other members of the Class would not have purchased or otherwise acquired BD common stock at artificially inflated prices if Defendants had disclosed all material information as required. Thus, to the extent that Defendants concealed or improperly failed to disclose material facts with regard to the Company and its business, Plaintiff and other members of the Class are entitled to a presumption of reliance in accordance with *Affiliated Ute*.

XI. THE STATUTORY SAFE HARBOR AND BESPEAKS CAUTION DOCTRINE ARE INAPPLICABLE

371. The Private Securities Litigation Reform Act's statutory safe harbor and/or the "bespeaks caution doctrine" applicable to forward-looking statements under certain circumstances do not apply to any of the materially false or misleading statements alleged herein.

372. None of the statements complained of herein was a forward-looking statement. Rather, each was a historical statement or a statement of purportedly current facts and conditions at the time each statement was made.

373. To the extent that any materially false or misleading statement alleged herein, or any portion thereof, can be construed as forward-looking, such statement was a mixed statement of present and/or historical facts and future intent, and is not entitled to safe harbor protection with respect to the part of the statement that refers to the present and/or past.

374. To the extent that any materially false or misleading statement alleged herein, or any portions thereof, may be construed as forward-looking, such statement was not accompanied by meaningful cautionary language identifying important facts that could cause actual results to differ materially from those in the statement or portion thereof. As alleged above in detail, given the then-existing facts contradicting Defendants' statements, any generalized risk disclosures made by Defendants were not sufficient to insulate Defendants from liability for their materially false or misleading statements.

375. To the extent that the statutory safe harbor may apply to any materially false or misleading statement alleged herein, or a portion thereof, Defendants are liable for any such false or misleading statement because at the time such statement was made, the speaker knew the statement was false or misleading, or the statement was authorized and approved by an executive officer of BD who knew that such statement was false or misleading.

XII. CAUSES OF ACTION

COUNT I
For Violations of Section 10(b) of The Exchange Act and Rule 10b-5 Promulgated Thereunder Against BD and The Individual Defendants

376. Plaintiff repeats and realleges each and every allegation set forth above as if fully set forth herein. This Count is brought against BD and the Individual Defendants pursuant to

Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder, 17 C.F.R. § 240.10b-5, on behalf of Plaintiff and all other members of the Class.

377. During the Class Period, BD and the Individual Defendants, while in possession of material adverse, non-public information, disseminated or approved the false or misleading statements and/or omissions alleged herein, which each defendant knew or recklessly disregarded were false or misleading in that they misrepresented material facts and/or failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading. Defendants carried out a plan, scheme, and course of conduct that: (i) deceived the investing public, including Plaintiff and other Class members, as alleged herein, regarding the intrinsic value of BD common stock; (ii) caused the price of BD common stock to be artificially inflated and/or maintained artificial inflation in the price of BD common stock; and (iii) caused Plaintiff and other members of the Class to purchase BD common stock at artificially inflated prices that did not reflect their true value. In furtherance of this unlawful scheme, plan, and course of conduct, BD and the Individual Defendants took the actions set forth herein while using the means and instrumentalities of interstate commerce and the facilities of a national securities exchange.

378. Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5 in that they, individually and in concert, directly and indirectly, knowingly and/or recklessly: (i) employed devices, schemes, and artifices to defraud; (ii) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements made not misleading; and (iii) engaged in acts, practices, and a course of business that operated as a fraud and deceit upon Plaintiff and other members of the Class in connection with their purchases of BD common stock in an effort to maintain artificially high market prices during the Class Period for BD

common stock in violation of Section 10(b) of the Exchange Act and Rule 10b-5. As alleged herein, the material misrepresentations contained in, or the material facts omitted from, Defendants' public statements included, but were not limited to, materially false or misleading statements and omissions during the Class Period, as alleged in Section VI.

379. Defendants are liable for all materially false or misleading statements and omissions of material fact alleged above in Section VI. By virtue of their high-level positions at the Company during the Class Period, the Individual Defendants were authorized to make public statements, and made public statements during the Class Period on BD's behalf. The Individual Defendants were privy to and participated in the creation, development, and issuance of the materially false or misleading statements alleged herein, and they and the Company disseminated information to the investing public that they either knew, or were reckless in not knowing, was materially false or misleading.

380. In addition to the duties of full disclosure imposed on Defendants as a result of making affirmative statements and reports to the investing public, Defendants also had a duty to disclose information required to update and/or correct their prior statements, misstatements, and/or omissions, and to update any statements or omissions that had become false or misleading as a result of intervening events. Further, Defendants had a duty to promptly disseminate truthful information that would be material to investors in compliance with the integrated disclosure provisions of the SEC, including accurate and truthful information with respect to the Company's operations, so that the market price of the Company's common stock would be based on truthful, complete, and accurate information.

381. Defendants' material misrepresentations and/or omissions were made knowingly, recklessly, and without a reasonable basis, for the purpose and effect of concealing from the

investing public the relevant truth, and misstating the intrinsic value of BD common stock. By concealing material facts from investors, Defendants maintained artificially inflated prices for BD common stock throughout the Class Period.

382. As a result of the dissemination of the materially false or misleading information and/or failure to disclose material facts, as set forth above, the market price of BD common stock was artificially inflated throughout the Class Period. In ignorance of the fact that market prices of BD common stock were artificially inflated, and relying directly or indirectly on the false or misleading statements made by BD and the Individual Defendants or upon the integrity of the market in which the securities traded, and/or in the absence of material adverse information that was known to or recklessly disregarded by BD and the Individual Defendants, Plaintiff and the other members of the Class purchased or otherwise acquired BD common stock during the Class Period at artificially inflated prices and were damaged thereby.

383. At the time of the material misrepresentations and/or omissions, Plaintiff and the other members of the Class were ignorant of their falsity, and believed them to be true. Had Plaintiff and the other members of the Class known the truth underlying Defendants' materially false or misleading statements alleged herein and the intrinsic value of BD common stock, Plaintiff and the other members of the Class would not have purchased or otherwise acquired BD common stock at the artificially inflated prices that they paid.

384. By virtue of the foregoing, BD and the Individual Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other Class members suffered damages in connection with their purchases and/or acquisitions of BD common stock during the Class Period.

COUNT II
For Violations of Section 20(a) of The Exchange Act
Against The Individual Defendants

385. Plaintiff repeats and realleges each and every allegation set forth above as if fully set forth herein. This Count is asserted against the Individual Defendants pursuant to Section 20(a) of the Exchange Act, 15 U.S.C. § 78t(a) on behalf of the Plaintiff and all other members of the Class.

386. During the Class Period, each of the Individual Defendants was a controlling person of BD within the meaning of Section 20(a) of the Exchange Act. By reason of their high-level positions at BD and their participation in and/or awareness of the Company's operations and/or intimate knowledge of the materially false or misleading statements and omissions of material fact in statements filed by the Company with the SEC and/or disseminated to the investing public, each of the Individual Defendants had the power to influence and control and did influence and control, directly or indirectly, the decision-making of the Company and its executives, including the content and dissemination of the various statements that Plaintiff contends were materially false or misleading.

387. Each of the Individual Defendants exercised day-to-day control over the Company and had the power and authority to cause BD to engage in the wrongful conduct complained of herein. In this regard, each of the Individual Defendants was provided with or had unlimited access to copies of the Company's reports, press releases, public filings, and other statements alleged by Plaintiff to be materially misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

388. Each of the Individual Defendants was a direct participant in making, and/or made aware of the circumstances surrounding, the materially false or misleading representations

and omissions during the Class Period, as alleged in Section VI. Accordingly, each Individual Defendant was a culpable participant in the underlying violations of Section 10(b) alleged herein.

389. As set forth above, BD violated Section 10(b) of the Exchange Act by its acts and omissions as alleged in this Complaint. By virtue of their positions as controlling persons of BD and, as a result of their own aforementioned conduct, each of the Individual Defendants is liable pursuant to Section 20(a) of the Exchange Act, jointly and severally with, and to the same extent as BD is liable under Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder, to Plaintiff and other members of the Class who purchased or otherwise acquired BD common stock during the Class Period at artificially inflated prices.

390. As a direct and proximate result of the Individual Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their purchases and/or acquisitions of BD common stock during the Class Period.

COUNT III
For Violations of Sections 10(b) and 20A of The Exchange Act and Rule 10b-5 Promulgated Thereunder for Insider Trading
Against Defendants Forlenza and Polen

391. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

392. This Count is asserted for violations of Section 20A of the Exchange Act, 15 U.S.C. § 78t-1(a) on behalf of Plaintiff and all other members of the Class who purchased shares of BD common stock contemporaneously with the sale of BD common stock by Defendants Forlenza and Polen while they were in possession of MNPI as alleged herein.

393. Section 20A(a) of the Exchange Act provides that "[a]ny person who violates any provision of . . . [the Exchange Act] or the rules or regulations thereunder by purchasing or selling a security while in possession of material, nonpublic information shall be liable . . . to any

person who, contemporaneously with the purchase or sale of securities that is the subject of such violation, has purchased . . . securities of the same class."

394. As set forth herein, Forlenza and Polen violated Section 10(b) of the Exchange Act, Rule 10b-5, and Section 20(a) of the Exchange Act for the reasons stated in Counts I and II above. Additionally, Forlenza and Polen further violated Exchange Act Section 10(b), Rule 10b-5, and Rule 10b5-1 (17 C.F.R. § 240.10b5-1) by selling shares of BD common stock while in possession of MNPI concerning the Alaris, as alleged herein, which information they had a duty to disclose, and which they failed to disclose in violation of Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder, as more fully alleged herein. *See* Section V.

395. Contemporaneously with Forlenza's insider sales of BD common stock on December 12, 2019, January 2, 2020, January 8, 2020, January 10, 2020, January 23, 2020, January 24, 2020, January 27, 2020, and January 28, 2020, Plaintiff purchased shares of BD common stock on a national securities exchange while Forlenza was in possession of adverse MNPI as alleged herein.

396. Contemporaneously with Polen's insider sales of BD common stock on December 16, 2019, Plaintiff purchased shares of BD common stock on a national securities exchange while Polen was in possession of MNPI as alleged herein.

397. Upon information and belief, other Class members purchased shares of BD common stock contemporaneously with Defendant Forlenza's and Polen's insider sales of BD common stock.

398. Plaintiff and other members of the Class have been damaged as a result of the violations of the Exchange Act alleged herein.

399. By reason of the violations of the Exchange Act alleged herein, Defendants Forlenza and Polen are liable to Plaintiff and other members of the Class who purchased shares of BD common stock contemporaneously with Forlenza's and Polen's respective sales of BD common stock during the Class Period.

400. Plaintiff and the other members of the Class who purchased contemporaneously with Forlenza's and/or Polen's respective insider sales of BD securities sales seek disgorgement by Forlenza and Polen, as applicable, of profits gained or losses avoided from Forlenza's and Polen's respective transactions in BD common stock contemporaneous with Plaintiff and other members of the Class.

401. This action was brought within five years after the date of the last transaction that is the subject of Forlenza's or Polen's violation of Section 20A, and, with respect to the underlying violations of Section 10(b) of the Exchange Act alleged in this Count and in Count I above, was brought within five years after the date of the last transaction that violated section 20A of the Exchange Act by Forlenza or Polen.

XIII. PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully prays for judgment as follows:

A. Determining that this action is a proper class action maintained under Rules 23(a) and (b)(3) of the Federal Rules of Civil Procedure;

B. Declaring and determining that Defendants violated the Exchange Act by reason of the acts and omissions alleged herein;

C. Awarding Plaintiff and the Class compensatory damages against all Defendants, jointly and severally, in an amount to be proven at trial together with prejudgment interest thereon;

D. Awarding Plaintiff and the Class their reasonable costs and expenses incurred in this action, including but not limited to, attorneys' fees and costs incurred by consulting and testifying expert witnesses; and

E. Granting such other and further relief as the Court deems just and proper.

XIV. JURY TRIAL DEMANDED

Plaintiff hereby demands a trial by jury.

Dated: October 29, 2021

Respectfully submitted,

CARELLA BYRNE CECCHI
OLSTEIN BRODY & AGNELLO, PC

s/ James E. Cecchi
James E. Cecchi
Donald A. Ecklund
5 Becker Farm Road
Roseland, NJ 07068-1739
Telephone: (973) 994-1700
Facsimile: (973) 994-1744
jcecchi@carellabyrne.com
decklund@carellabyrne.com

Liaison Counsel for the Putative Class

KESSLER TOPAZ
MELTZER & CHECK, LLP
Sharan Nirmul
David A. Bocian
Joshua E. D'Ancona
Vanessa M. Milan (admitted *Pro Hac Vice*)
280 King of Prussia Road
Radnor, PA 19087
Telephone: (610) 667-7706
Facsimile: (610) 667-7056
snirmul@ktmc.com
dbocian@ktmc.com
jdancona@ktmc.com
vmilan@ktmc.com

Counsel for Lead Plaintiff Industriens Pensionsforsikring A/S and Lead Counsel for the Putative Class

CERTIFICATE OF SERVICE

I, James E. Cecchi, hereby certify that on October 29, 2021, I caused a true and correct copy of the foregoing Third Amended Class Action Complaint to be filed electronically with the Clerk of the Court using the ECF system. Notice of this filing will be sent to counsel of record by operation of the Court's electronic filing system. I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Dated: October 29, 2021

s/ James E. Cecchi

James E. Cecchi
CARELLA BYRNE CECCHI
OLSTEIN BRODY & AGNELLO, PC
5 Becker Farm Road
Roseland, NJ 07068-1739
Telephone: (973) 994-1700
Facsimile: (973) 994-1744
jcecchi@carellabyrne.com

Liaison Counsel for the Putative Class